Exhibit A

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION

This document relates to:

Case No. 17-OP-45004 (N.D. Ohio)

THE COUNTY OF CUYAHOGA, OHIO, et al.,

Plaintiffs,

vs.

PURDUE PHARMA L.P., et al.

Defendants.

Case No. 17-OP-45090 (N.D. Ohio)

THE COUNTY OF SUMMIT, OHIO, et al.,

Plaintiffs,

vs.

PURDUE PHARMA L.P., et al.

Defendants.

MDL No. 2804

Case No. 17-md-2804

Judge Dan Aaron Polster

CONFIDENTIAL

EXPERT REPORT OF M. LAURENTIUS MARAIS, Ph.D.

May 10, 2019

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I. Introduction and Background

1. I am a Vice President and Principal Consultant at William E. Wecker Associates, Inc., a consulting firm that specializes in applied mathematical and statistical analysis. I hold a Ph.D. degree and master's degrees in business administration, mathematics, and statistics from Stanford University. I have taught and conducted scholarly research while serving on the faculties of the University of Chicago and Stanford University. I am a fellow of the Royal Statistical Society and a member of the Society for Industrial and Applied Mathematics, the American Economics Association, and the American Accounting Association, among other professional societies. I have extensive experience in applying statistical and mathematical theory and methods and in reviewing and assessing the validity of applied mathematical and statistical studies, inferences, and conclusions, including those based on applications of regression analysis. These qualifications and a list of my professional publications are shown in my curriculum vitae, which is appended to this report as Attachment A.

2. A list of cases in which I have testified as an expert at trial or by deposition in the last four years is appended to this report as Attachment B. Wecker Associates bills for my work in this matter at a rate of $750 per hour.

3. I understand that the Plaintiffs in this matter allege that certain "Marketing Defendants," including Johnson & Johnson and Janssen Pharmaceuticals, Inc. (collectively, "Janssen"), "created a public health crisis and a public nuisance" by mounting "a massive marketing campaign premised on false and incomplete information."[1] Plaintiffs describe the Marketing Defendants' activities in support of this "massive marketing campaign" as follows:[2]

[1] Corrected Second Amended Complaint, *In Re National Prescription Opiate Litigation, The County of Summit, Ohio, et al. vs. Purdue Pharma LP, et al.*, USDC Northern District of Ohio Eastern

- The Marketing Defendants utilized various channels to carry out their marketing scheme of targeting the medical community and patients with deceptive information about opioids:

  (1) "Front Groups" with the appearance of independence from the Marketing Defendants;

  (2) so-called "key opinion leaders" ("KOLs"), that is, doctors who were paid by the Marketing Defendants to promote their pro-opioid message;

  (3) CME programs controlled and/or funded by the Marketing Defendants;

  (4) branded advertising;

  (5) unbranded advertising;

  (6) publications;

  (7) direct, targeted communications with prescribers by sales representatives or "detailers"; and

  (8) speakers bureaus and programs.

4. In this report I refer to these complained-of activities as the "Conduct."

5. Plaintiffs support their claims with opinions from several experts, including Dr. Meredith Rosenthal.[3] Dr. Rosenthal characterizes her assignment as follows:[4]

> [Make the following determinations] … to a reasonable degree of certainty in the area of healthcare economics and econometrics:
>
> • *Manufacturer substantial contribution causation.* … [W]hether the combined effect of the Defendant manufacturers' promotion of prescription opioids since 1995 was a substantial contributing factor in causing an increase in the use of prescription opioids in the Bellwether communities
>
> • *Manufacturer "but for" causation.* … [W]hether the increase in the use of prescription opioids in the Bellwether communities since 1995 would have occurred … "but for" the allegedly unlawful promotion of these products by the Defendant manufacturers

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Division, MDL No. 2804, Case No. 17-md-2804 referring to Case No. 18-op-45090(N.D. Ohio), May 18, 2018 (the "Summit Complaint"), ¶¶ 9–10. See also Second Amended Complaint, *In Re National Prescription Opiate Litigation, The County of Cuyahoga, Ohio, et al. vs. Purdue Pharma LP, et al.*, USDC Northern District of Ohio Eastern Division, MDL No. 2804, Case No. 17-md-2804 referring to Case No. 17-OP-45004 (N.D. Ohio), May 18, 2018 (the "Cuyahoga Complaint"). The Cuyahoga and Summit complaints are part of a multi-district litigation pending in the Northern District of Ohio. See *In re: National Prescription Opiate Litigation*, MDL No. 2804, Case No. 1:17-MD-2804.

[2] Summit Complaint, ¶¶ 350–351.

[3] Expert Report of Rosenthal, *In Re National Prescription Opiate Litigation, The County of Cuyahoga, Ohio, et al. vs. Purdue Pharma LP, et al.*, USDC Northern District of Ohio Eastern Division, MDL No. 2804, Case No. 17-md-2804, March 25, 2019 (the "Rosenthal Report").

[4] Op. cit. ¶ 8.

> • *Extent of "but for" causation*. … [T]he quantum of increase in the use of prescription opioids in the Bellwether communities that resulted from the Defendant manufacturers' promotion of prescription opioids since 1995
>
> • *Sensitivity to particular manufacturers*. … [E]xplain and, if necessary, articulate the sensitivity [if any, of conclusions "to the potential … that any one or more of the Defendant manufacturers is found not to have engaged in unlawful marketing"] in quantitative terms such that your conclusions may be used by other experts in reports that use your results to estimate damages.

6. In sum, Dr. Rosenthal's assignment requires detecting, isolating, and measuring the change, if any, in the quantity of opioid MMEs dispensed *due to* the Conduct. While several of the Plaintiffs' experts address the nature and amount of harms allegedly caused by the Conduct, only Dr. Rosenthal develops a regression equation that purportedly quantifies the alleged causal impact of the Conduct in terms of incremental dispensing of MMEs specifically "due to" or "attributable to" Conduct increments.[5] Several of Plaintiffs' other experts cite and rely upon this portion of Dr. Rosenthal's work.[6] Thus, Dr. Rosenthal's regression modeling provides crucial support for the work of Plaintiffs' other experts and for Plaintiffs' claims overall.

7. Dr. Rosenthal states that the purpose of her "direct approach" using the statistical method of "regression analysis"[7] is "to quantify directly the causal

[5] With her "direct approach" (Rosenthal Report, Sec. VIII) Dr. Rosenthal attempts to measure quantitatively the impact of a proxy for Conduct on the quantity of MMEs dispensed using regression analysis. Her "indirect approach" (Rosenthal Report, Sec. IX) also employs regression analysis but does not attempt this measurement of the effect of specific Conduct increments on the quantity of MMEs dispensed.

[6] Expert Report of Professor David Cutler, In *Re National Prescription Opiate Litigation*, USDC Northern District of Ohio Eastern Division, MDL No. 2804, Case No. 17-md-2804, March 25, 2019; Expert Report of Professor Jonathan Gruber, In *Re National Prescription Opiate Litigation*, USDC Northern District of Ohio Eastern Division, MDL No. 2804, Case No. 17-md-2804, March 25, 2019; and Expert Report of Professor Thomas McGuire Damages to Bellwethers, In *Re National Prescription Opiate Litigation*, USDC Northern District of Ohio Eastern Division, MDL No. 2804, Case No. 17-md-2804, March 25, 2019.

[7] Concerning "regression analysis" generally, see Rubinfeld, Daniel L., Reference Guide on Multiple Regression, in *Reference Manual on Scientific Evidence, 3rd Edition,* Federal Judicial Center, 2011.

relationship between promotion and sales."[8] I understand that the "causal relationship" that Dr. Rosenthal aims to measure is the *change* in MME dispensing that would result from any given *change* in promotion, i.e., in the Conduct, while allowing all other conditions to evolve coherently as they would have if that change had in fact occurred. Using her "direct approach" regression model, Dr. Rosenthal purports to "explain" changes over time in the quantities of MME's actually dispensed and purports to "predict" what those quantities would have been but for the Conduct.

8. Counsel for Janssen asked me to review Dr. Rosenthal's report, as well as the Expert Reports of Professors Jonathan Gruber and David Cutler, and to comment and respond to their related opinions as appropriate. In particular, counsel asked me to opine on whether Dr. Rosenthal has provided valid support for her opinions by accurately isolating and measuring the impact of Conduct increments on the quantity of MMEs dispensed.

9. In connection with this assignment I have reviewed the materials listed in Attachment C.

[8] Rosenthal Report, ¶ 10. Dr. Rosenthal's terminology elsewhere confirms that she means to estimate *causal* effects. See Rosenthal Report ¶ 8 (referring to the "the quantum of increase in the use of prescription opioids in the Bellwether communities that resulted *from* the Defendant manufacturers' promotion of prescription opioids since 1995" [italics added]). See also Rosenthal Report ¶ 64 (where Dr. Rosenthal states that her regression modeling serves "two purposes," including that it "indicate[s] that in economic terms there is a *causal relationship* between the Defendants' promotion and prescriptions of opioids so that if the allegations of misconduct are proven true, *impact* can be found." [italics added]).

II. Opinions and Bases

A. Dr. Rosenthal's regression modeling does not measure reliably any effect of the Conduct on the quantity of MMEs dispensed at retail

1. Dr. Rosenthal's preferred "direct approach" regression model[9] provides no reliable measure of the impact of detailing contacts on the quantity of MMEs dispensed at retail

10. Regression analysis is a statistical procedure for finding an equation that "explains" the value of an outcome variable—in the case of Dr. Rosenthal's "direct approach" regression modeling, prescription opioid MMEs[10] dispensed at retail by month from 1993 to May 2018—as a function of the values of "explanatory variables." In this matter Dr. Rosenthal chose to limit her explanatory variables to the discounted cumulative stock of past and present detailing contacts[11] for each month (expressed in three variations,[12] captured in three separate variables), and an aggregate price index[13] for each month.[14]

11. The "explaining" is done by a regression equation that multiplies the value of each "explanatory" variable by a corresponding constant "coefficient," and then sums the results. (By convention the variables doing the explaining—the "explanatory" or "independent" variables—are written on the right-hand side of an "equal sign," and the variable to be explained—the "dependent" variable—is written on the left-hand side.)

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[9] Dr. Rosenthal's Model B is her "preferred" model. She indicates that Model A "do[es] not fit the underlying data well." Model C is the same as Model B except for five additional explanatory variables, whose effects Dr. Rosenthal determines are jointly "not statistically different from zero." (Rosenthal Report at ¶¶ 68 and 70–74 and p. D6).
[10] "These drugs are manufactured and promoted by the Defendants and other non-Defendants." (Rosenthal Report Attachment D, p. D.3).
[11] Rosenthal Report ¶ 62.
[12] Ibid. ¶¶ 71–72 and 74.
[13] Ibid. ¶ 60.
[14] Ibid. ¶¶ 68–74. "These drugs are manufactured and promoted by the Defendants and other non-Defendants." Rosenthal Report Attachment D, p. D.3.

12. Given a table of data representing a set of corresponding numeric values of the left-hand-side and right-hand-side variables, a mathematical procedure encoded in computer software determines the numeric values of the "coefficients" that multiply the explanatory variables so that the resulting regression equation produces "fitted values" that agree as closely as possible with the value of the dependent variable on the left that is to be "explained." With access to electronic computers this part of a regression analysis is all too easy; the computational procedure of regression analysis can be applied mechanically to virtually any set of columns of numbers to produce statistical "estimates" of the "coefficients" of the "explanatory variables."

13. However, the more difficult and nuanced part of a well-conceived "regression analysis" is establishing that such calculated coefficient estimates are, in fact, valid measurements of meaningful concepts—such as the "impact" of the discounted stock of detailing contacts on the quantity of MMEs dispensed at retail. The answer to this more complex question depends on a rigorous review of considerations and assumptions about the structure of the data and the process that generated it.

14. An old example, often used in statistics courses, illustrates this point well. The data displayed in the following figure suggests that the proportion of Church of England marriages among all marriages in England and Wales from 1866 to 1911 "explains" the rate of mortality in England and Wales in the same years quite well.

Figure 1: Reproduction of Figure 1 from Yule (1926)[15]

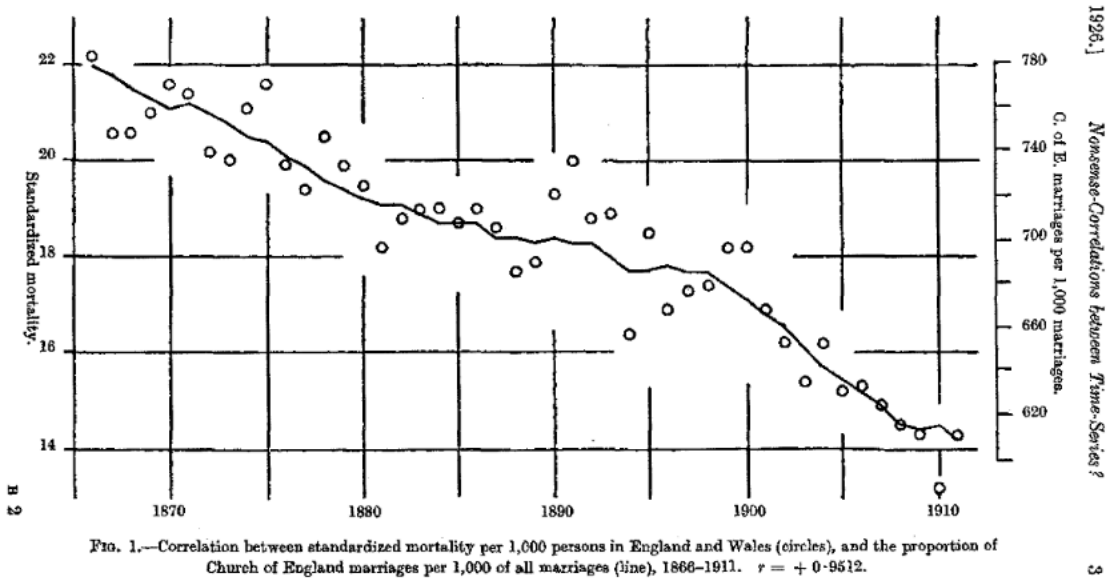


FIG. 1.—Correlation between standardized mortality per 1,000 persons in England and Wales (circles), and the proportion of Church of England marriages per 1,000 of all marriages (line), 1866–1911. $r = +0{\cdot}9512$.

15. The relationship between these two variables has an "R-squared" of greater than 0.90 (90%), and it is highly "statistically significant."

16. Dr. Rosenthal's measures of statistical success, including the important-sounding "R-squared" measure and the "statistical significance" of the coefficient of the "explanatory variable" (proportion of Church of England marriages), reach seemingly impressive levels in this example. Yet the notion that one can derive from these data a meaningful quantification of the *causal* impact of the proportion of Church of England marriages on mortality is nonsensical on its face. Yule put it as follows:

[15] Yule, G Udny. "Why Do We Sometimes Get Nonsense-Correlations Between Time-Series?" Journal of the Royal Statistical Society, Vol. 89, No. 1 (Jan. 1926), pp. 1–63.

> Now I suppose it is possible, given a little ingenuity and good-will, to rationalize very nearly anything. And I can imagine some enthusiast arguing that the fall in the proportion of Church of England marriages is simply due to the Spread of Scientific Thinking since 1866, and the fall in mortality is also clearly to be ascribed to the Progress of Science; hence both variables are largely or mainly influenced by a common factor and consequently ought to be highly correlated. But most people would, I think, agree with me that the correlation is simply sheer nonsense; that it has no meaning whatever; that it is absurd to suppose that the two variables in question are in any sort of way, however indirect, causally related to one another.

17. Nonsense regressions of this kind are not always so easy to recognize and unmask. In many situations there is no immediately obvious intuitive basis for recognizing that a regression equation cannot be relied on to determine how one variable (e.g., the quantity of MMEs dispensed) will respond if another variable (e.g., the number of detailing contacts) is changed. And the nonsense content of a regression equation need not be as complete as in the Church of England example: a candidate explanatory variable may be at least superficially plausible as a potential cause of the dependent variable. However, as I explain below, the scholarly literature of statistics provides guidance and insight into the nature of such nonsense regressions.

18. The variable that Dr. Rosenthal seeks to explain (MMEs dispensed at retail by month) and the variable she chooses to do the explaining (the discounted cumulative stock of detailing contacts) are both examples of "time-series data." Time-series data are series of values that evolve over time, generally exhibiting noticeable patterns or trends in relation to past values, rather than being the product of a causal process that repeats itself in each period of observation

independently of its previous realizations (and therefore free of any genuine pattern or trend).[16]

19. Commonplace examples of time-series data are consumer price indices, stock market indices, and the gross national product. Dr. Rosenthal's dependent variable (monthly MMEs dispensed at retail) and key explanatory variable (the monthly discounted stock of detailing contacts) are also time-series data. It is characteristic of time-series data that the *order* of the observations is meaningful: that is, essential information is lost if the data set is scrambled. For example, Dr. Rosenthal's data on MME's dispensed at retail and the discounted stock of detailing contacts are both linked to the natural ordering of a series of calendar months.

20. It has been well known to statisticians for generations, at least since it was discussed at length in Yule's 1926 article,[17] that one time series can often be well "explained" by another—even in situations where that "explanation" is meaningless nonsense. In fact, the problem that gives rise to the Church-marriage/mortality nonsense discussed above is that both the proportion of Church of England marriages and mortality rates are time series: that is, they exhibit noticeable trends in relation to past values.

21. More recent reviews and analyses of the problem of nonsense results from a regression of one time series on another include Granger and Newbold's important "Spurious Regressions in Econometrics," Phillips's "Understanding Spurious Regressions in Econometrics," and Noriega and Ventosa-Santaulària's "Spurious Regression and Trending Variables."[18] These authors show, using modern statistical

[16] "Time-series regression, which is the particular technique I use in this case, examines patterns over time for a single unit of analysis (here, the United States retail pharmaceutical market) to capture a dynamic causal relationship." (Rosenthal Report, ¶ 58)
[17] Yule, op. cit.
[18] Granger, C W J, and P Newbold. "Spurious Regressions in Econometrics." *Journal of Econometrics* 2 (1974): 1–10. Phillips, P C B. "Understanding Spurious Regressions in Econometrics." *Journal of Econometrics* 33 (1986): 311–40. Noriega, A E, and Ventosa-Santaulària, D. "Spurious Regression and Trending Variables." *Oxford Bulletin of Economics and Statistics* 69 (2007): 439-444.

methods, "how nonsense regressions relating economic time series can arise" and provide indicia that warn of and allow testing for the nonsense. Dr. Rosenthal appears not to have applied any such test in this case. Simply put, she never validated her model.

22. However, there is another, more direct way to test whether Dr. Rosenthal's preferred "direct approach" regression model[19] can be relied upon as a reliable proof and quantification of any causal impact[20] of the monthly discounted stock of detailing contacts on the monthly quantity of MMEs dispensed at retail. For this purpose I have performed a sequence of sensitivity analyses of Dr. Rosenthal's preferred regression model, that is, regression analyses, identical in form to Dr. Rosenthal's preferred Model B, except that I substituted alternative right-hand-side variables for Dr. Rosenthal's own discounted stock of detailing contacts to "explain" the quantity of MMEs dispensed at retail. The results of these regression calculations are summarized in Table 1 below. The first of my regression calculations, which is summarized in column [A] of the table, simply replicates Dr. Rosenthal's model B.

[19] Dr. Rosenthal's "Model B" (Rosenthal Report, ¶¶ 68, 71-71, and 74).
[20] Rosenthal Report ¶ 37.

Table 1

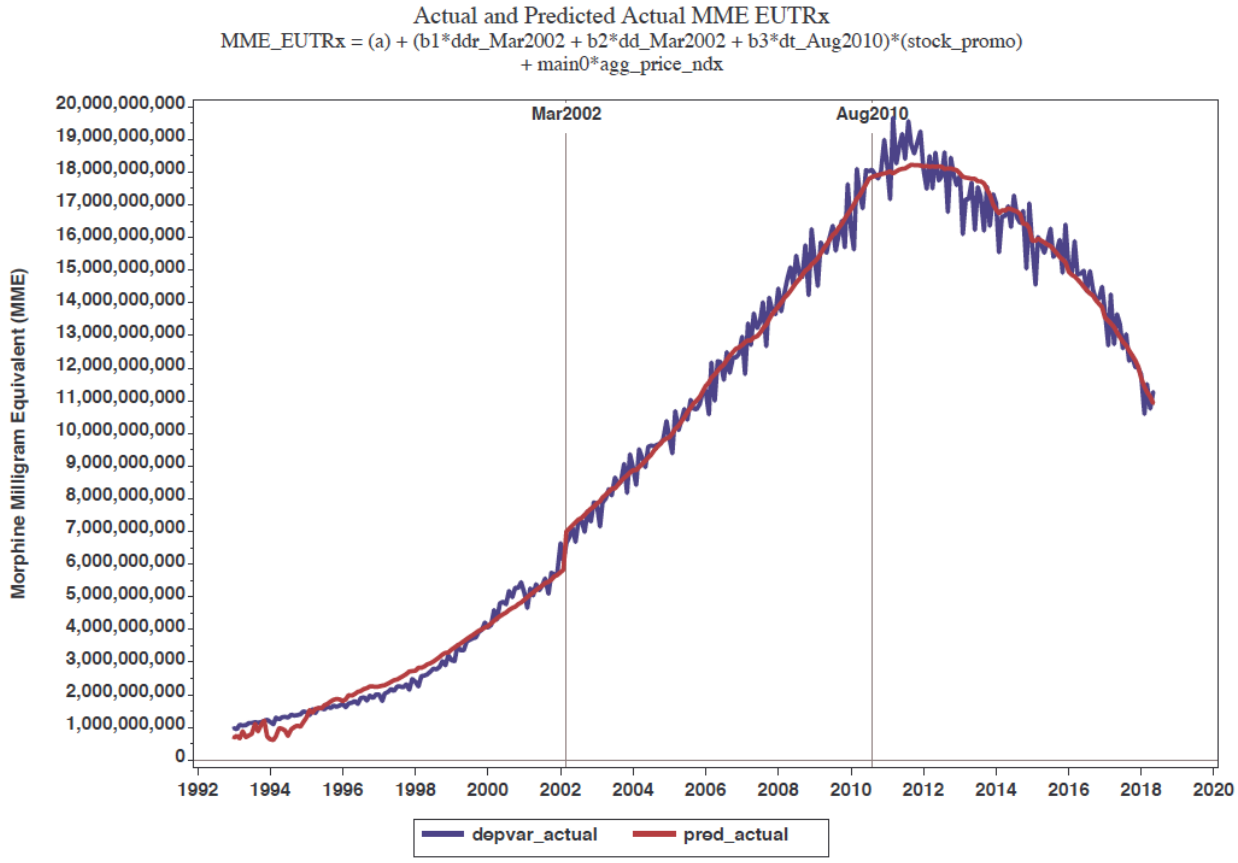
Rosenthal Model B Variations

Regression Estimates: Impact of [Explanatory Factor] on Sales in MMEs, 1993-2018

Parameters		Model A		Model B		Model C		[A]		[B]		[C]		[D]		[E]	
Param.	Label	Estimate	Sig.	Estimate	Sig.	Estimate	Sig.	Model B Replication		*Reverse* Contacts History		*Scramble* Contacts History		"Contacts" = constant 40,000 for all months		"Contacts" = Mauna Loa CO_2 (ppm×100)	
α	Constant	5,667,453,793	***	2,447,050,075	***	2,823,448,831	***	2,447,050,075	***	2,300,597,120	***	1,610,266,163	***	1,604,148,858	***	1,593,428,999	***
β	Stock of Promotion	2,965	***	-		-											
β_1	Stock of Promotion*Regime Dummy until Mar2002	-		934	***	878	***	934	***	1,038	***	1,006	***	841	***	93,672	***
β_2	Stock of Promotion*Dummy from Mar2002	-		1,111	***	1,064	***	1,111	***	1,344	***	1,294	***	1,067	***	118,706	***
β_3	Stock of Promotion*Dummy Trend from Aug2010	-		-8	***	-8	***	-8	***	-10	***	-10	***	-8	***	-870	***
δ	Depreciation Rate Constant	0.0005		-0.0067	***	-0.0070	***	-0.0067	***	-0.0061	***	-0.0057	***	-0.0060	***	-0.0058	***
γ_1	Consensus Statement From AAPM/APS 01/1998	-		-		-208,998,427											
γ_2	Federation of State Medical Boards Guidelines 01/1999	-		-		434,599,302	**										
γ_3	JCAHO pain standards released 01/2001(*)	-		-		4,733,839											
γ_4	OxyContin Reformulation 08/2010	-		-		107,939,744											
γ_5	Hydrocodone Rescheduling 10/2014	-		-		552,145,343	***										
γ_6	Aggregate Price Index	-7,689,846,168	***	-1,947,298,967	***	-2,233,428,201	***	-1,947,298,967	***	-1,334,245,762	***	-1,095,330,437	**	-1,084,146,014	**	-1,069,151,818	**
RSquare		0.8811		0.9937		0.9939		0.9937		0.9937		0.9935		0.9936		0.9937	
AdjRSq		0.8799		0.9936		0.9937		0.9936		0.9936		0.9934		0.9935		0.9936	

23. Figure 2 below displays graphically the monthly dispensed MMEs and "fitted values" (i.e., the values "predicted" by the fitted regression equation) from my replication of Dr. Rosenthal's Model B.

Figure 2: Replication of Rosenthal Figure D.2[21]
(Omitting Predicted MMEs for the But-For Scenario)



Source: IQVIA NPA, ARCOS, and CDC.

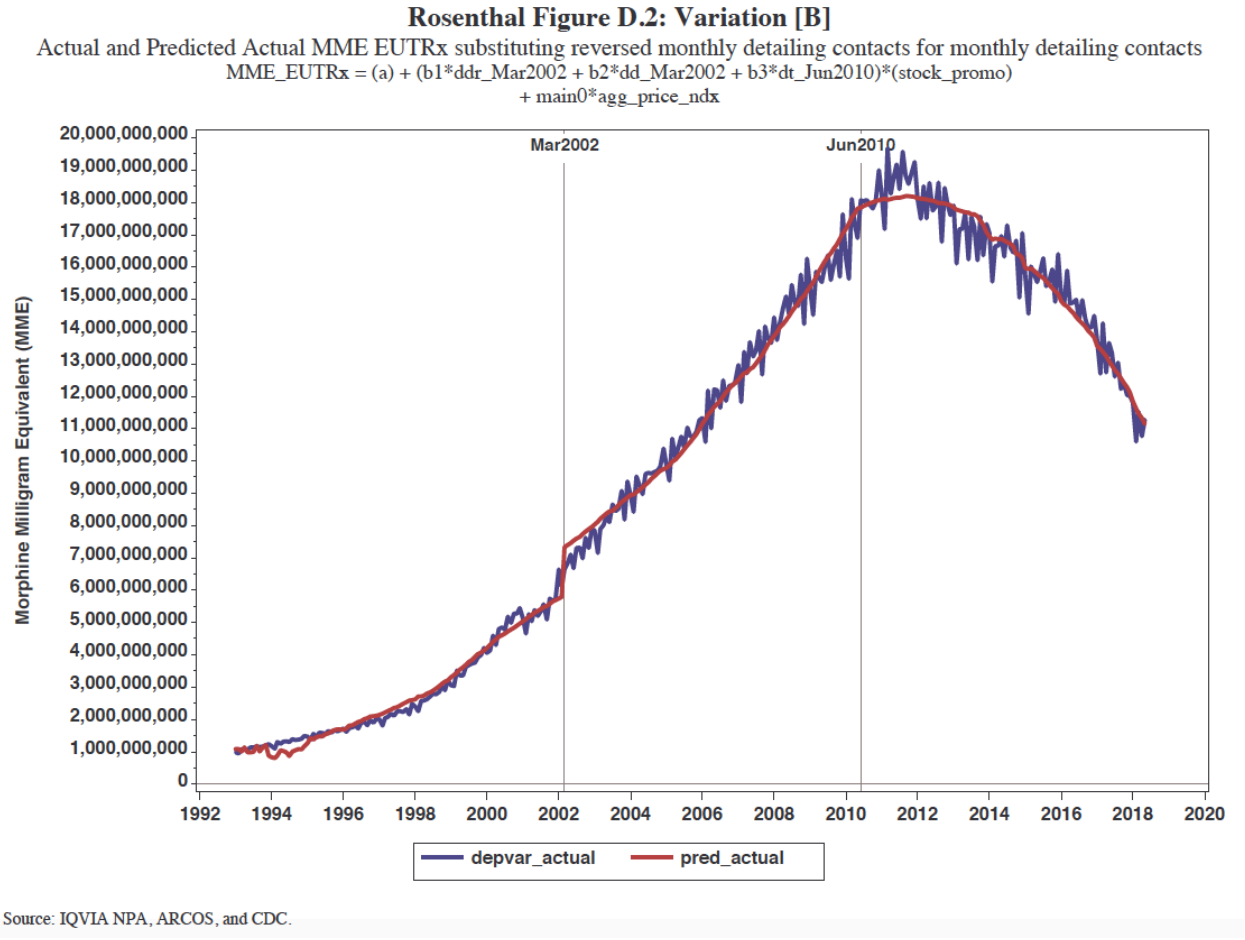
24. For my first sensitivity analysis of Dr. Rosenthal's baseline regression model—summarized in column [B] of Table 1—I again performed the same form of regression calculation as Dr. Rosenthal but substituted for Dr. Rosenthal's explanatory variable (the discounted stock of detailing contacts) the pseudo-stock of contacts obtained after *reversing* Dr. Rosenthal's monthly counts of detailing

[21] This figure replicates Dr. Rosenthal's Figure D.2 except for omitting the values predicted by the Model B regression equation for Dr. Rosenthal's but-for scenario, which are shown in green in her Figure D.2.

contacts. In other words, for this alternative regression calculation I exchanged Dr. Rosenthal's counts of detailing contacts for January, February, March, April, and May 2018[22] with the counts for May, April, March, February, and January 1993, respectively, and so on. The indicators of statistical significance of this modified model (see highlighted asterisks) and its apparent goodness of fit (see highlighted R-squared statistic) are identical to those of Dr. Rosenthal's own model B. Moreover, a graphical display of the modified model's ability to replicate and "predict" the trajectory of MMEs dispensed at retail (see Figure 3) is practically indistinguishable from Dr. Rosenthal's own corresponding figure (see the portion of Rosenthal Figure D.2 replicated in Figure 2 above). (This result would be unsurprising if the pattern of growth and decline of monthly detailing contacts were symmetrical over the interval from January 2013 to May 2018, but Dr. Rosenthal's Figure 4 shows that that is *not* the case).

[22] Dr. Rosenthal's Model B regression data begin in January 1993 and end in May 2018.

Figure 3



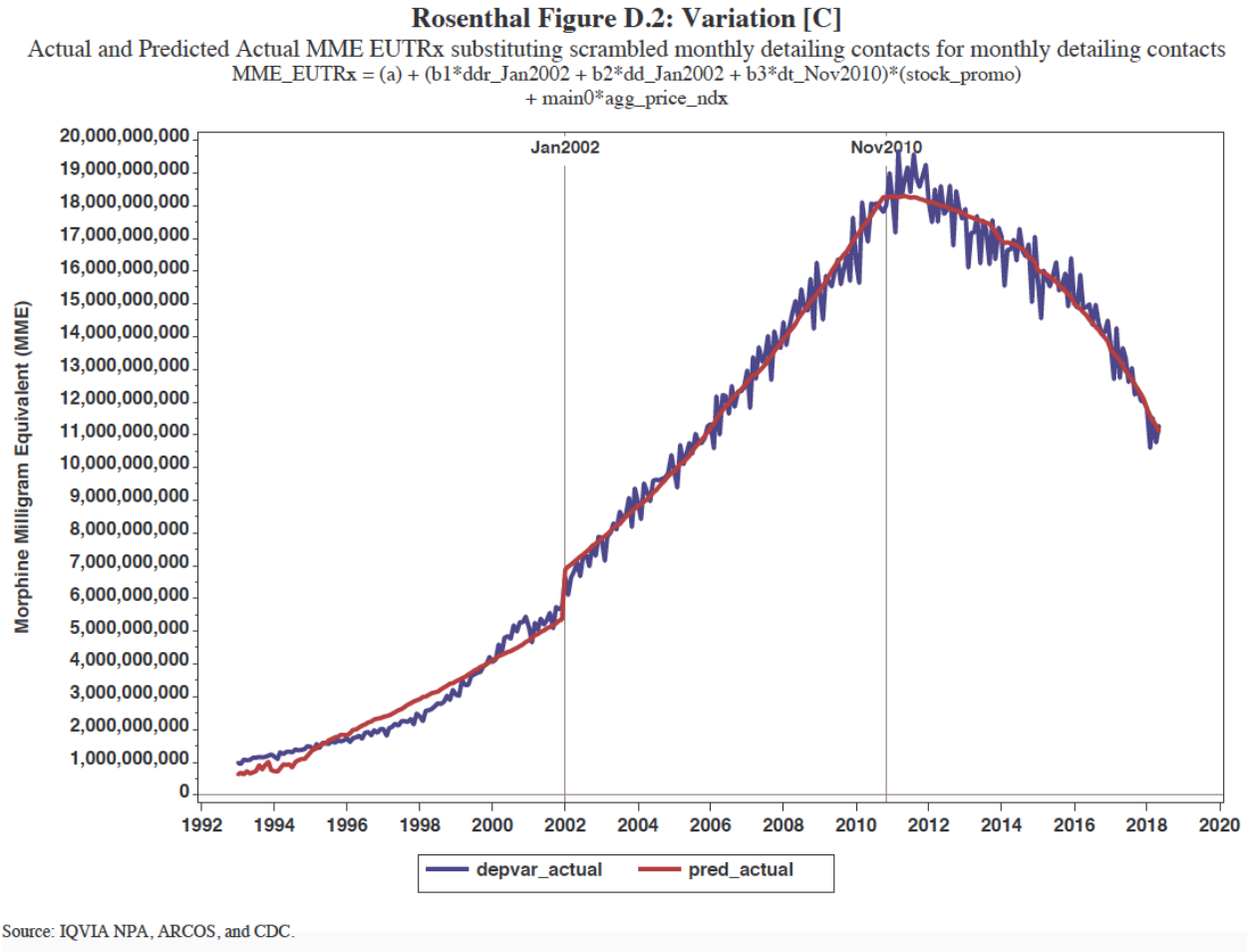
Source: IQVIA NPA, ARCOS, and CDC.

25. That MMEs dispensed at retail are "explained" as well by the *reversed* history of monthly detailing contacts as by Dr. Rosenthal's actual history of monthly detailing contacts suggests that Dr. Rosenthal's regression results may be largely an artifact of her computational procedure, along the lines of the "spurious" regressions discussed above, rather than a reliable measure of the *change* in MMEs *caused* by a *change* in detailing contacts.

26. For my second sensitivity analysis of Dr. Rosenthal's baseline regression model—summarized in column [C] of Table 1—I again performed the same form of regression calculation as Dr. Rosenthal but substituted for Dr. Rosenthal's explanatory variable (discounted stock of detailing contacts) the pseudo-stock of

contacts obtained from *scrambling* (i.e., permuting randomly) Dr. Rosenthal's monthly counts of detailing contacts (as if each monthly count of detailing contacts had been written on an index card and the deck of cards reassembled after being dropped down a stairwell). The indicators of statistical significance of this modified model (see highlighted asterisks) and its apparent goodness of fit (see highlighted R-squared statistic) are essentially identical to those of Dr. Rosenthal's own model B. Moreover, a graphical display of the modified model's ability to replicate and "predict" the trajectory of MMEs dispensed at retail (see Figure 4) is practically indistinguishable from Dr. Rosenthal's own corresponding figure (see Rosenthal Figure D.2).

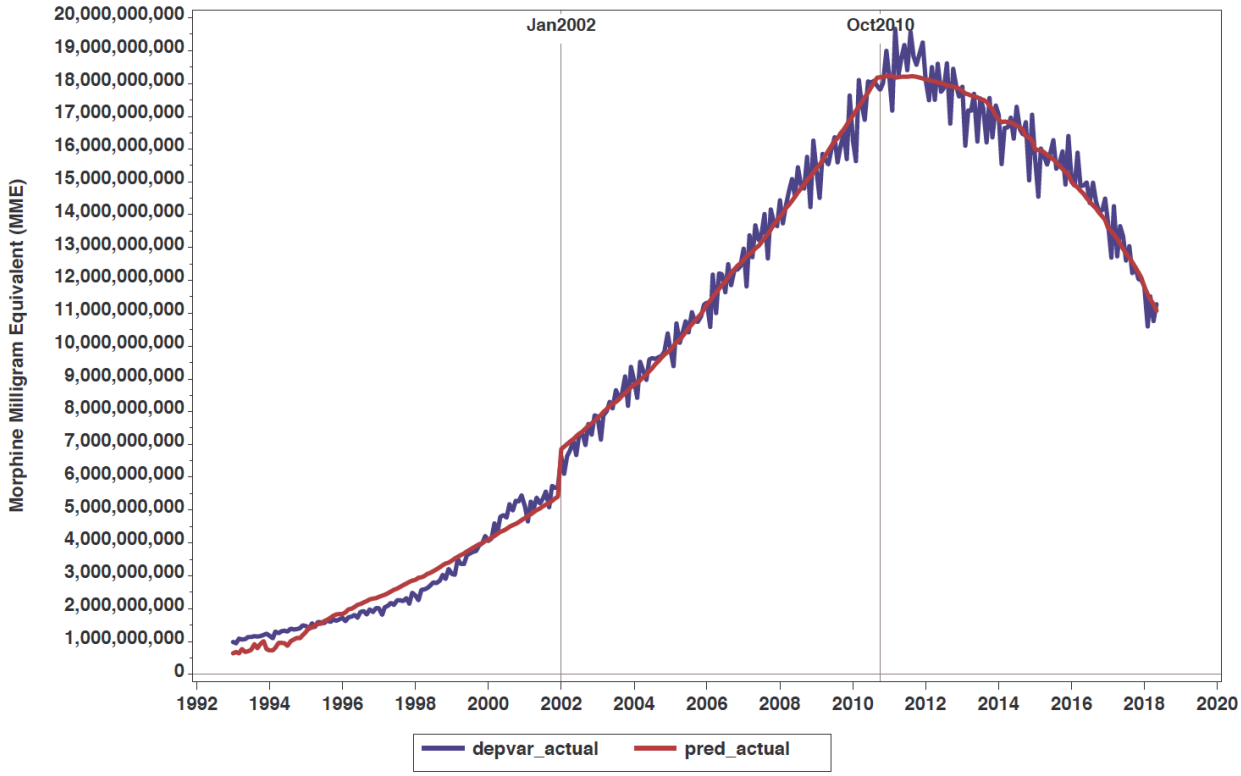
Figure 4



27. That MMEs dispensed at retail are "explained" as well by the *scrambled* history of monthly detailing contacts as by Dr. Rosenthal's actual history of monthly detailing contacts adds further support for the hypothesis that Dr. Rosenthal's regression results are largely an artifact of her computational procedure, along the lines of the "spurious" regressions discussed above, rather than a reliable measure of the *change* in MMEs *caused* by a *change* in detailing contacts.

28. For my third sensitivity analysis of Dr. Rosenthal's baseline regression model—summarized in column [D] of Table 1—I again performed the same form of regression calculation as Dr. Rosenthal but substituted for Dr. Rosenthal's explanatory variable (the discounted stock of detailing contacts) the pseudo-stock of contacts obtained setting each monthly count of contacts to the arbitrary value of 40,000. The indicators of statistical significance of this modified model (see highlighted asterisks) and its apparent goodness of fit (see highlighted R-squared statistic) are again essentially identical to those of Dr. Rosenthal's own model B. Moreover, a graphical display of the modified model's ability to replicate and "predict" the trajectory of MMEs dispensed at retail (see Figure 5) is again practically indistinguishable from Dr. Rosenthal's own corresponding figure (see Rosenthal Figure D.2).

Figure 5
Rosenthal Figure D.2: Variation [D]
Actual and Predicted Actual MME EUTRx substituting 40,000 for monthly detailing contacts
MME_EUTRx = (a) + (b1*ddr_Jan2002 + b2*dd_Jan2002 + b3*dt_Oct2010)*(stock_promo)
+ main0*agg_price_ndx



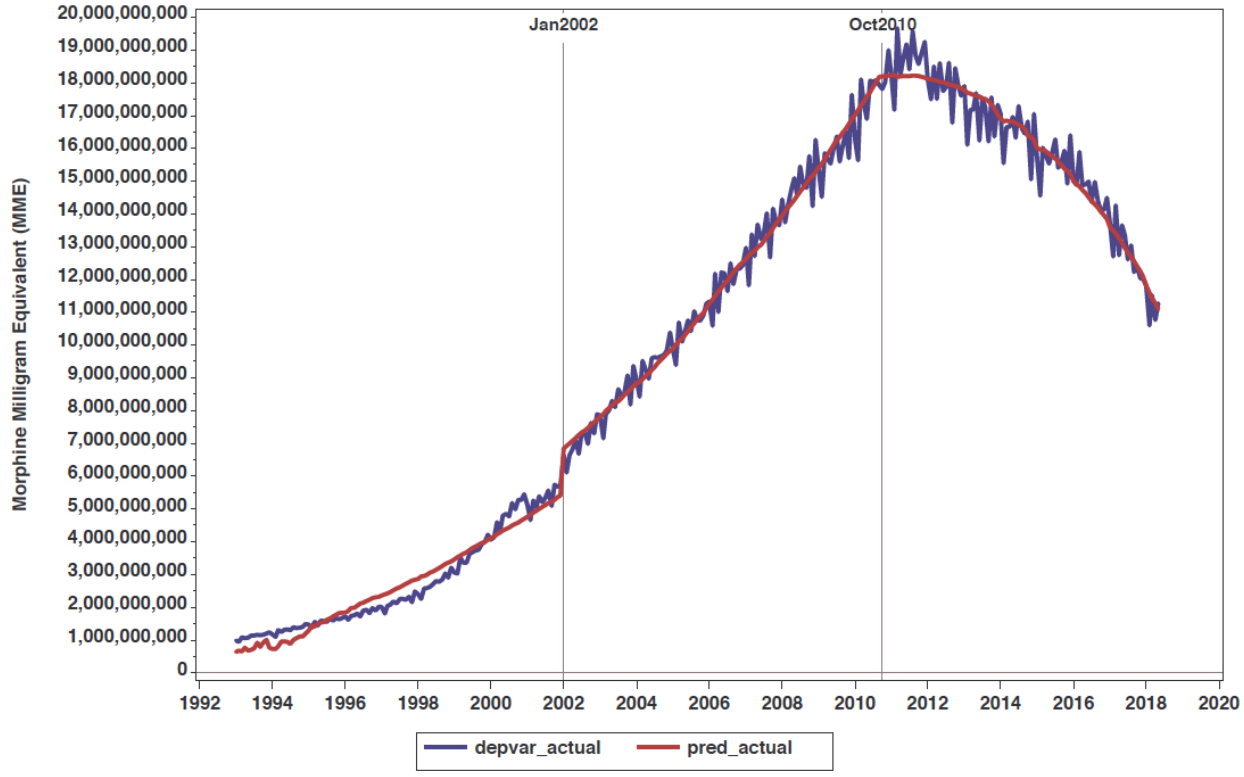
Source: IQVIA NPA, ARCOS, and CDC.

29. That MMEs dispensed at retail are "explained" as well by a single, arbitrarily selected pseudo-count of monthly detailing contacts as by Dr. Rosenthal's actual history of monthly detailing contacts further supports the hypothesis that Dr. Rosenthal's regression results are largely an artifact of her computational procedure, along the lines of the "spurious" regressions discussed above, rather than a reliable measure of the *change* in MMEs *caused* by a *change* in detailing contacts.

30. For my final sensitivity analysis of Dr. Rosenthal's baseline regression model—summarized in column [E] of Table 1—I again performed the same form of regression calculation as Dr. Rosenthal but substituted for Dr. Rosenthal's explanatory variable (discounted stock of detailing contacts) the pseudo-stock of contacts obtained by substituting for monthly counts of detailing contacts the

monthly average measurements of carbon dioxide (CO_2) concentrations at the Mauna Loa observatory. The indicators of statistical significance of this modified model (see highlighted asterisks) and its apparent goodness of fit (see highlighted R-squared statistic) are again essentially identical to those of Dr. Rosenthal's own model B. Moreover, a graphical display of the modified model's ability to replicate and "predict" the trajectory of MMEs dispensed at retail (see Figure 6) is again practically indistinguishable from Dr. Rosenthal's own corresponding figure (see Rosenthal Figure D.2).

Figure 6
Rosenthal Figure D.2: Variation [E]
Actual and Predicted Actual MME EUTRx substituting monthly average Mauna Loa CO_2 for monthly detailing contacts
MME_EUTRx = (a) + (b1*ddr_Jan2002 + b2*dd_Jan2002 + b3*dt_Oct2010)*(stock_promo)
+ main0*agg_price_ndx



Source: IQVIA NPA, ARCOS, and CDC.

31. That MMEs dispensed at retail are "explained" as well by carbon dioxide concentrations at Mauna Loa as by Dr. Rosenthal's history of monthly detailing contacts, viewed in combination with the previous sensitivity analyses and the

additional analyses disclosed in Attachment E, establishes beyond reasonable controversy that Dr. Rosenthal's regression results are an artifact of her computational procedure, along the lines of the "spurious" regressions discussed above, rather than a reliable measure of the *change* in MMEs *caused* by a *change* in detailing contacts.

32. In sum, Dr. Rosenthal has not established that her "direct approach" regression analysis in this proceeding provides any reliable indication—or any reliable measure—of the causal impact on MMEs dispensed at retail of changes in the numbers of detailing contacts. Accordingly, Dr. Rosenthal's "direct approach" regression analysis is fundamentally incapable of supporting her opinions or those of other experts in this case.

2. Dr. Rosenthal's "direct approach" regression is incapable of isolating and measuring the effects of distinct components of the Conduct

33. The Conduct complained of by the Plaintiffs in this matter comprises eight distinct components (see ¶ 3 above). Only the seventh of the eight components of the Conduct involves detailing ("communications with prescribers by sales representatives or 'detailers'"). Clearly, the range of promotional programs complained of in this case is much broader than detailing alone.

34. Dr. Rosenthal recognizes this. She states that the Marketing Defendants "used a *panoply* of both branded and unbranded marketing tactics to increase opioid sales. … [D]ocuments produced in discovery show many examples of such *promotional efforts beyond detailing* [footnote omitted] that I understand Plaintiffs intend to prove were illegal, … [italics added]."[23]

35. Nevertheless, for her "direct approach" regression model, Dr. Rosenthal relies entirely on counts of detailing contacts—corresponding to this single component of the Conduct—as the explanatory variable to represent the Marketing Defendants'

[23] Rosenthal Report ¶ 56.

"promotional efforts."[24] She devotes a single paragraph of her report to justifying use of this "proxy" variable to represent Defendants' "total promotional effort,"[25] that is, the entire suite of activities comprising the Conduct.

36. Dr. Rosenthal proffers three justifications for relying on this proxy. These are: the vague generalization that "detailing is by far the dominant form of promotion"; the unsupported claim that "it is reasonable to expect" that efforts devoted to "*some* [emphasis added]" of the seven Conduct components other than detailing will follow the "course" of detailing; and that she was unable to obtain adequate data to represent promotional activity other than detailing. In sum, Dr. Rosenthal provides no empirical support or any other substantial basis for her ipse dixit that "[f]rom an econometric standpoint, detailing is a good proxy for total promotional effort."

37. Under the heading of "*Comcast* Considerations," Dr. Rosenthal claims, concerning her "direct approach," that "the calculation of impact due to misconduct can be readily revised *to conform to* ***any*** *ruling by the court* [emphasis added]."[26] She then illustrates this claim with examples involving the removal of defined subsets of detailing contacts from the category of illegitimate promotional activity. However, since her "direct approach" regression analysis does not comprehend explicitly any component of the Conduct other than detailing, it is inherently incapable of isolating and accounting for the causal impact, if any, of any component of the Conduct other than detailing. Thus, Dr. Rosenthal's "direct approach" is inherently *incapable*, in fact, of being revised to conform to any ruling by the court pertaining to any component of the Conduct *other* than detailing.

[24] Rosenthal Report ¶ 56 and p. D6.
[25] Ibid. ¶ 56.
[26] Ibid. at D6.

38. Dr. Rosenthal claims further that using detailing as a proxy for the Conduct renders her calculations "conservative," again without substantial support. This claim too is a Rosenthal ipse dixit.

3. Dr. Rosenthal's "indirect approach" regression modeling provides no reliable measure of the causal effect solely of the Conduct on the quantity of MMEs dispensed at retail

39. Dr. Rosenthal's "indirect approach" regression modeling is designed to measure simultaneously and in aggregate the *joint* effect of *all* factors that contributed to changing prescribing patterns for opioids after 1997. Thus, any "residual" effect it measures is not limited to the impact, if any, of the Marketing Defendants' efforts to promote their opioids. Further, Dr. Rosenthal conspicuously omits any mention of "*Comcast* Considerations" in the context of her discussion of her "indirect approach." This is because the method she proffers is inherently incapable of being limited to measuring the effect of any court-determined *subset* of Conduct components. Indeed, the method she proffers doesn't even distinguish between the effects of promotional activities of defendants and non-defendants.

40. In sum, while Dr. Rosenthal's "indirect approach" avoids some of the flaws of her "direct approach," neither approach comes close to reliably isolating and measuring the effect, if any, of the Conduct on a statistically reliable basis.

4. Dr. Rosenthal's modeling is incapable of isolating and measuring on a statistically reliable basis the effects, if any, of Janssen activities included in the Conduct

41. In the preceding discussion I set forth the bases for my opinion that Dr. Rosenthal's report in this matter *fails* to establish that her purported regression modeling (in either of its forms) isolates and measures any causal effect of the Conduct on a reasonably reliable statistical basis for the Marketing Defendants in aggregate. For essentially the same reasons her modeling fails to do so for any individual Defendant including, in particular, Janssen.

B. ARCOS data from the U.S. EPA shows that Janssen's share of all opioids shipped to dispensing facilities in Cuyahoga and Summit Counties, Ohio was small

42. The U.S. DEA ARCOS data shows a steady decrease in Janssen's share of all prescription opioids[27] shipped to dispensing facilities[28] in Cuyahoga and Summit Counties, Ohio from January 2006 to December 2014. Over the eight-year period covered in the ARCOS data, Janssen's total share based on net MMEs of prescription opioid shipments to dispensing facilities in Cuyahoga and Summit Counties averaged 1.6 percent.[29, 30] See Attachment D Table D.1. For Cuyahoga County alone the corresponding average was 1.4 percent (Attachment D Table D.2), and for Summit County alone it was 1.9 percent (Attachment D Table D.3).

[27] Opioids tracked and provided by the U.S. Drug Enforcement Agency from their Automation of Reports and Consolidated Orders System (ARCOS) data base includes the following opioid drug names: buprenorphine, Codeine, dihydrocodeine, fentanyl, hydrocodone, hydromorphone, meperidine, morphine, opium powdered, oxycodone, oxymorphone, and tapentadol. Janssen opioids are Duragesic (fentanyl), Nucynta (tapentadol), Nucynta ER (tapentadol), Tylenol with codeine (codeine), and Tylox (oxycodone). See tab13/janssen.market.share.lst.

[28] Dispensing facilities include chain and retail pharmacies, hospitals, clinics, practitioners, and teaching institutions. See tab13/janssen.market.share.lst.

[29] Tabulations of morphine milligram equivalents reflects net ARCOS transactions (sales, dispositions, transfers, purchases, returns, and unsolicited returns) by indicated time period, where buyer state is Ohio, counties are Summit and Cuyahoga, and buyer business type is not an analytical lab, distributor, exporter, manufacturer, or reverse distributor.

[30] Conversions from grams as tracked by ARCOS are converted to morphine milligram equivalents (MME) using the Centers for Disease Control (CDC) database https://www.cdc.gov/drugoverdose/resources/data.html (accessed May 3, 2019) and the Centers for Medicaid and Medicare Services opioid morphine conversion factors https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Opioid-Morphine-EQ-Conversion-Factors-April-2017.pdf. (accessed May 3, 2019).

C. OARRS data from the Ohio Board of Pharmacy shows a low rate of involvement of Janssen opioids in "doctor shopping"

43. In the course of my work on this matter I received data from the Ohio Automated Rx Reporting System (OARRS) for the period 2008–2018.[31] Counsel for Janssen asked me to analyze the OARRS data for indications of "doctor shopping" involving three pertinent Janssen opioids: Duragesic, Nucynta, and Nucynta ER.

44. I understand that the State of Ohio defines a doctor shopper as a patient filling prescriptions for opioids from five or more prescribers at five or more pharmacies in a single month.[32] For the analysis I report here I defined as an episode of doctor shopping any instance of a single patient filling prescriptions for opioids from five or more distinct prescribers within a 30 day window. Because this definition does not consider the number of distinct pharmacies filling the prescriptions, such episodes would be not recognized as doctor shopping by the State of Ohio. Thus, the definition I adopt here is conservative compared to that of the State of Ohio for the purpose of tallying doctor shopping episodes.

45. Based on this conservative definition, my analysis of the OARRS data—which is summarized in Table 2 below—reveals very little involvement of Duragesic, Nucynta, and Nucynta ER in doctor shopping. Specifically, out of 55,594 prescriptions for Duragesic, Nucynta, and Nucynta ER in the OARRS data, I identified only 154, or 0.28% (= 154 / 55,594), as being involved in a doctor shopping episode. These 154 prescriptions represent 0.13% (= 154 / 114,870) of all prescriptions involved in a doctor shopping episode. The corresponding percentages for Duragesic prescriptions alone were 0.31% (= 39 / 12,636) and 0.034% (= 39 /

[31] Ohio Automated Prescription Reporting System is created by the State of Ohio Board of Pharmacy. OARRS collects information on all outpatient prescriptions for controlled substances. https://www.ohiopmp.gov.
[32] "Doctor Shopper=Patient filling prescriptions for 5+ prescribers at 5+ pharmacies in 1 month." See www.ohiopmp.gov/State.aspx (accessed May 3, 2019).

114,870); for Nucynta alone 0.28% (= 103 / 37,022) and 0.09% (= 103 / 114,870); and for Nucynta ER alone 0.20% (= 12 / 5,936) and 0.01% (= 12 / 114,870).

Table 2

Ohio Automated Rx Reporting System (OARRS) Data 2008–2018

Prescriptions with Indications of "Doctor Shopping"

Janssen Drugs	Prescriptions Involved in Doctor Shopping	Total Prescriptions (by Drug)	Percent of Total Prescriptions	Total Prescriptions Involved in Doctor Shopping (All Labelers)	Percent of Total Prescriptions Involved in Doctor Shopping
Duragesic	39	12,636	0.309%	114,870	0.034%
Nucynta IR	103	37,022	0.278%	114,870	0.090%
Nucynta ER	12	5,936	0.202%	114,870	0.010%
Total	154	55,594	0.277%	114,870	0.134%

Patients with Indications of "Doctor Shopping"

Janssen Drugs	Patients Involved in Doctor Shopping	Total Patients (by Drug)	Percent of Total Patients	Total Patients Involved in Doctor Shopping (All Labelers)	Percent of Total Patients Involved in Doctor Shopping
Duragesic	26	1,528	1.702%	10,401	0.250%
Nucynta IR	67	9,972	0.672%	10,401	0.644%
Nucynta ER	6	1,121	0.535%	10,401	0.058%
Total	97	12,083	0.803%	10,401	0.933%

46. Viewed alternatively in terms of the patients (rather than prescriptions) involved in doctor shopping episodes, the OARRS data again reveals very little involvement of Duragesic, Nucynta, and Nucynta ER in doctor shopping. Out of 12,083 patients who filled at least one prescription for Duragesic, Nucynta, or Nucynta ER, I identified only 97, or 0.80% (= 97 / 12,083), as being involved in a doctor shopping episode. These 97 patients represent 0.93% (= 97 / 10,401) of all

patients involved in a doctor shopping episode. The corresponding percentages for patients who filled at least one Duragesic prescription were 1.70% (= 26 / 1,528) and 0.25% (= 26 / 10,401); for Nucynta 0.67% (= 67 / 9,972) and 0.64% (= 67 / 10,401); and for Nucynta ER 0.54% (= 6 / 1,121) and 0.058% (= 6 / 10,401).

III. Conclusion

47. In sum, the process through which Dr. Rosenthal developed the regression models proffered in her report provides no assurance that these models are capable of measuring reliably the effect on the quantity of MMEs dispensed at retail of the Conduct.

48. The opinions I have reached in this case to date are based on information, data, and analyses of the types typically and reasonably relied upon by experts in my areas of expertise. In particular, my opinions are based on my background, knowledge, and experience in applied mathematics and statistics. I hold each of the opinions expressed in this report to a reasonable degree of scientific certainty. I may do additional work and I may revise or refine my opinions in light of additional information or analyses. In particular, I received the transcript of Dr. Rosenthal's recent deposition in this matter only three days ago and have not yet had the opportunity to review it fully. More generally, I understand that I may be asked to assess and respond to opinions or exhibits that may be offered by the parties at or before trial.

M. L. Marais

M. Laurentius Marais, Ph. D.

Attachment A: Curriculum Vitae of M. Laurentius Marais

May 2019

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EDUCATION:

Ph.D. Stanford University (Business Administration, Mathematics), 1985
M.S. Stanford University (Statistics), 1983
M.S. Stanford University (Mathematics), 1976
B.Sc. Stellenbosch University (Mathematics, Applied Mathematics, Computer Science), 1973

EMPLOYMENT:

1993 to date Vice President, William E. Wecker Associates, Inc.
1994-1998 Stanford University, Consulting Professor, School of Law
1992-1993 Senior Consultant, now Principal Consultant, William E. Wecker Associates, Inc.
1982-1991 University of Chicago, Instructor, later Assistant and Associate Professor, Graduate School of Business.

ACTIVITIES:

Editorial Board, Journal of Accounting Research, 1987-1992

Refereed for: The Accounting Review
Contemporary Accounting Research
Journal of Accounting and Economics
Journal of Accounting Research
Journal of Business and Economic Statistics
Journal of Financial Research
Journal of Money, Credit and Banking

Member of: American Accounting Association
American Economic Association
American Statistical Association
Royal Statistical Society
Mathematical Association of America
Society for Industrial and Applied Mathematics

PUBLICATIONS and WORKING PAPERS:

"The experimental design of classification models: an application of recursive partitioning and bootstrapping to commercial bank loan classifications," (with James M. Patell and Mark A. Wolfson), Journal of Accounting Research, 1984.

"An application of the bootstrap method to the distribution of squared, standardized market model prediction errors," Journal of Accounting Research, 1984.

"An analysis of a multivariate regression model in the context of a regulatory event study by computer intensive resampling," Working Paper, Institute of Professional Accounting, University of Chicago, July 1986.

"A note on the algebraic and statistical properties of the multivariate market model," Working Paper, Institute of Professional Accounting, University of Chicago, September 1986.

"On drawing inferences about market reactions to the regulation of accounting for oil and gas exploration: An application of computer intensive resampling methods," Working Paper, Institute of Professional Accounting, University of Chicago, September 1986.

"On detecting abnormal returns to a portfolio of nonsynchronously traded securities," Working Paper, Institute of Professional Accounting, University of Chicago, October 1986.

"Reduced demands on recovery room resources with Diprivan compared to thiopental-isoflurane," (with Michael W. Maher et al.), Anesthesiology Review, January/February 1989.

"Wealth effects of going private for senior securities," (with Katherine Schipper and Abbie J. Smith), Journal of Financial Economics, 1989.

"Consequences of going-private buyouts for public debt and preferred stock: 1974 to 1985," (with Katherine Schipper and Abbie J. Smith), in Proceedings of the 25th Annual Conference on Bank Structure and Competition: Banking System Risk - Charting a New Course, Federal Reserve Bank of Chicago, 1989.

"Discussion of 'Post-earnings-announcement drift: Delayed price response or risk premium?'," Journal of Accounting Research, 1989.

"Using relative productivity assessments for allocating housestaff to departments," (with Michael W. Maher, Michael F. Roizen, et al.), Medical Care, 1990.

"An adaptable computer model of the economic effects of alternative anesthetic regimens in outpatient surgery," (abstract; with Michael W. Maher et al.), Anesthesiology (Supplement), September 1990.

"On the finite sample performance of estimated generalized least squares in seemingly unrelated regressions: nonnormal disturbances and alternative standard error estimators," Working Paper, Institute of Professional Accounting, University of Chicago, January 1991.

"Exploiting tax attributes of spinoffs to structure takeovers and takeover-related defenses," (with Katherine Schipper), Working Paper, Institute of Professional Accounting, University of Chicago, August 1991.

"Technological innovation and firm decision-making: accounting, finance and strategy," (with Paul J. H. Schoemaker), Working Paper, Institute of Professional Accounting, University of Chicago, September 1991.

"Process-oriented activity-based costing," (with Michael W. Maher), Working Paper, Institute of Professional Accounting, University of Chicago, June 1992.

"A field study on the limitations of activity-based costing when resources are provided on a joint and indivisible basis" (with Michael W. Maher), Journal of Accounting Research, 1998.

"Correcting for omitted-variables and measurement-error bias in regression with an application to the effect of lead on IQ" (with William E. Wecker), Journal of the American Statistical Association, June 1998.

"Event study methods: detecting and measuring the security price effects of disclosures and interventions" (with Katherine Schipper), in Litigation Services Handbook: The Role of the Financial Expert, 2005 Cumulative Supplement, 3rd Ed., John Wiley & Sons.

"Estimating Cost Behavior" (with Michael W. Maher), in Handbook of Cost Management, 2005, 2nd Ed., John Wiley & Sons.

"Audit Committee Financial Literacy: A Work in Progress" (with Douglas J. Coates and Roman L. Weil), Journal of Accounting Auditing and Finance, March 2007.

"Statistical Estimation of Incremental Cost from Accounting Data" (with William E. Wecker and Roman L. Weil), in Litigation Services Handbook: The Role of the Financial Expert, 2017, 6th Ed., John Wiley & Sons.

Attachment B: Previous Testimony of M. Laurentius Marais

M. Laurentius Marais
Deposition and Trial Testimony
January 2015 – May 2019

1. Northrop Grumman v. Aon Risk Insurance Services West. California Superior Court of Los Angeles County. Case No. BC453927.
2. In Re Chinese-Manufactured Drywall Products Liability Litigation. United States District Court for the Eastern District of Louisiana. MDL 2047.
3. Hernandez v. Crown Equipment. Superior Court of Loundes County, Georgia. Civil Action No. 2013CV1154.
4. World Car v. Hyundai Motor America. Texas Department of Motor Vehicles, Motor Vehicle Division. SOAH Docket No. 608-14-1208 LIC; MVD Docket No. 14-0006 LIC.
5. In Re Sears, Roebuck and Co. Front-Loading Washer Products Liability Litigation. United States District Court for the Northern District of Illinois, Eastern Division. Case No. 06-cv-7023.
6. Spidle v. Pentair. United States District Court for the Southern District of Texas, Houston Division. Civil Action No. 4:15-cv-361.
7. Doan v. State Farm. California Superior Court of Santa Clara County. Case No. 1-08-CV-129264.
8. Dyson v. Sharkninja. United States District Court for the Northern District of Illinois, Eastern Division. Case No. 1:14-cv-09442.
9. Dzielak v. Whirlpool. United States District Court for the District of New Jersey. Civil Action No. 12-cv-0089.
10. DaVita Healthcare Partners v. Baxter Healthcare. District Court, Denver County, Colorado. Case No. 2015CV032714.
11. Neale v. Volvo Cars of North America. United States District Court for the District of New Jersey, Newark Division. Case No. 2:10-cv-04407-JLL-JAD.
12. In Re Copaxone 40 MG Consolidated Cases. United States District Court for the District of Delaware. Civil Action No. 1:14-cv-001171-GMS.
13. Glaxosmithkline v. Teva Pharmaceuticals. United States District Court for the District of Delaware. Civil Action No. 14-878-LPS-CJB.
14. In Re Testosterone Replacement Therapy Products Liability Litigation. United States District Court for the Northern District of Illinois. MDL No. 2545. Master Docket Case No. 1:14-cv-01748.
15. Guarantee Trust Life Insurance v. Platinum Services, American Arbitration Association. Case No. 01-15-0005-9328.
16. Fairfield Sentry Limited v. PriceWaterhouseCoopers. Ontario Superior Court of Justice. Case No. CV-14-10550-00CL.

17. Graci v. Omega Flex. United States District Court for the District of Connecticut. Case No. 3:15-cv-00513.
18. The People of the State of California v. General Motors. California Superior Court of Orange County. Case No. 30-2014-00731038-CU-BT-CXC.
19. Wolf v Thomas. California Superior Court of Sonoma County. Case No. SCV-251845.
20. Mitchell v AbbVie. United States District Court for the Northern District of Illinois. Case No. 14 C 9178.
21. Couch v. AbbVie. Circuit Court of Cook County, Illinois. Case No. 2014 L 005859.
22. Super98 v. Delta Air Lines. United States District Court for the Northern District of Georgia, Atlanta Division. Case No. 1:16-cv-1535-LMM.
23. Risperdal and Invega Product Liability Cases. California Superior Court of Los Angeles County. Judicial Council Coordination Proceeding No. 4775.
24. Konrad v. AbbVie. United States District Court for the Northern District of Illinois, Eastern Division. Case No. 15 C 966.
25. Jordan v. Nationstar and Federal Housing Finance Agency, United States District Court for the Eastern District of Washington. Case No. 2:14-CV-00175-TOR.
26. Cotromano v. United Technologies and Adinolfe v. United Technologies. United States District Court for the Southern District of Florida. Case Nos. 13-CV-80928-RYSKAMP and 10-80840-CIV-KLR.
27. Nolte v AbbVie. United States District Court for the Northern District of Illinois, Eastern Division. Case No. 14 C 8135.
28. In Re General Motors LLC Ignition Switch Litigation. United States District Court for the Southern District of New York. Case No. 14-MD-2543.
29. Pinares v. United Technologies. United States District Court for the Southern District of Florida. Case No. 10-CIV-80883-Marra/Hopkins.
30. Reinard v. Crown Equipment. Iowa District Court for Black Hawk County. Case No. LACV130248.
31. Snyder v. California Insurance Guarantee Association. California Superior Court of Alameda County. Case No. RG-13-666656.
32. United States v. J-M Manufacturing. Case No. CV 6-55-GW (cf. No. 5:06-cv-00055-GW-PJW) (C.D. Cal.), Phase 2
33. State of Oklahoma v. Purdue Pharma. District Court of Cleveland County. Case No. CJ-2017-816.
34. Williams v. Crown Equipment. Superior Court of New Jersey, Camden County. Case No. L-511-16.

Attachment C: Documents Considered

Documents Considered

1. Corrected Second Amended Complaint, *In Re National Prescription Opiate Litigation, The County of Summit, Ohio, et al. vs. Purdue Pharma LP, et al.*, USDC Northern District of Ohio Eastern Division, MDL No. 2804, Case No. 17-md-2804 referring to Case No. 18-op-45090(N.D. Ohio), May 18, 2018.

2. Second Amended Complaint, *In Re National Prescription Opiate Litigation, The County of Cuyahoga, Ohio, et al. vs. Purdue Pharma LP, et al.*, USDC Northern District of Ohio Eastern Division, MDL No. 2804, Case No. 17-md-2804 referring to Case No. 17-OP-45004 (N.D. Ohio), May 18, 2018.

3. Expert Report of Rosenthal, *In Re National Prescription Opiate Litigation*, USDC Northern District of Ohio Eastern Division, MDL No. 2804, Case No. 17-md-2804, March 25, 2019, materials cited therein, errata to report produced May 2, 2019, and the following electronic files produced:
   - March 26, 2019 Rosenthal, Prof. Meredith.zip
   - April 16, 2019 Rosenthal - Supplemental Materials recd 4-16-2019.zip
   - April 19, 2019 2019-04-19 - Rosenthal, McCann.zip
   - April 22, 2019 2019-04-22 - Missing Rosenthal Reliance.zip
   - May 2, 2019 Preferred_Model_Comcast_final_errata.sas

4. Videotaped Deposition of Meredith B. Rosenthal, Ph.D., In Re National Prescription Opiate Litigation, All Cases, USDC Northern District of Ohio Eastern Division, MDL No. 2804, Case Na. 1:17-md-2804, May 4–5, 2019.

5. Expert Report of Professor David Cutler, *In Re National Prescription Opiate Litigation*, USDC Northern District of Ohio Eastern Division, MDL No. 2804, Case No. 17-md-2804, March 25, 2019, materials cited therein, and the following electronic files produced:
   - March 25, 2019 Cutler, Dr. David.zip
   - April 18, 2019 Cutler Literature.zip

6. Expert Report of Professor Jonathan Gruber, *In Re National Prescription Opiate Litigation*, USDC Northern District of Ohio Eastern Division, MDL No. 2804, Case No. 17-md-2804, March 25, 2019, materials cited therein, and the following electronic files produced:
   - March 25, 2019 Gruber.zip
   - April 18, 2019 Gruber Literature.zip
   - May 3, 2019 2019-05-03 Gruber & Keller.zip

7. Expert Report of Professor Thomas McGuire Damages to Bellwethers, *In Re National Prescription Opiate Litigation*, USDC Northern District of Ohio Eastern Division, MDL No. 2804, Case No. 17-md-2804, March 25, 2019, materials cited therein, and the following electronic file produced:
   - March 25, 2019 McGuire, Dr. Thomas (BELL).zip

8. National Oceanic and Atmospheric Administration Atmospheric CO2 at Mauna Loa Observatory data ftp://aftp.cmdl.noaa.gov/products/trends/co2/co2_mm_mlo.txt (accessed April 27, 2019).

9. Centers for Disease Control (CDC) opioid morphine conversion factors data, cdc_mme_table_sept2018.sas7bdat, https://www.cdc.gov/drugoverdose/resources/data.html (accessed May 3, 2019).

10. Centers for Medicaid and Medicare Services opioid morphine conversion factors data, https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Opioid-Morphine-EQ-Conversion-Factors-April-2017.pdf (accessed May 3, 2019).

11. The American Hospital Formulary Service (AHFS) Pharmacologic-Therapeutic Classification, http://www.mgh.org/Content/Uploads/UP%20Health%20System%20-%20Marquette/files/formulary/AHFS%20Pharmacologic-Therapeutic%20Classification%20(2012).pdf (accessed May 3, 2019).

12. Federal Drug Administration (FDA) National Drug Code (NDC) / National Health Related Items Code (NHRIC) labeler codes, ndc_nhric_labeler_codes_05_03_2019.xlsx, https://www.fda.gov/industry/structured-product-labeling-resources/ndcnhric-labeler-codes (accessed May 3, 2019).

13. U.S. Drug Enforcement Agency data from DEA's Automation of Reports and Consolidated Orders System (ARCOS) Registrant Handbook, Version 1.0, August 1997. www.deadiversion.usdoj.gov/arcos/handbook/full.pdf (accessed May 3, 2019).

14. Confidential U.S. Drug Enforcement Agency data from DEA's Automation of Reports and Consolidated Orders System (ARCOS) data files:
confidential_arcos_20060101-20141231_all_states_20180621.txt
confidential_arcos_20060101-20141231_all_states_20180625.txt
confidential_arcos_20060101-20141231_oh_wv_il_al_mi_fl_20180419_01.txt
…
confidential_arcos_20060101-20141231_oh_wv_il_al_mi_fl_20180419_14.txt

15. Ohio Automated Prescription Reporting System (OARRS) https://www.ohiopmp.gov/State.aspx (accessed May 3, 2019).

16. Confidential Ohio Automated Prescription Reporting System (OARRS) data created by the State of Ohio Board of Pharmacy. Ohio BOP 20190221 Vol 1 & 2.zip:
BOP_MDL 5th Production_000001.txt
…
BOP_MDL 5th Production_000044.txt

17. Depomed Announcement April 2, 2015

https://www.jnj.com/media-center/press-releases/janssen-pharmaceuticals-inc-completes-divestiture-of-us-license-rights-to-nucynta-tapentadol-nucynta-er-tapentadol-extended-release-tablets-and-nucynta-tapentadol-oral-solution-to-depomed-inc (accessed May 3, 2019)

https://www.prnewswire.com/news-releases/depomed-announces-closing-of-acquisition-of-us-rights-to-nucynta-tapentadol-nucynta-er-tapentadol-extended-release-tablets-and-nucynta-tapentadol-oral-solution-from-janssen-pharmaceuticals-inc-for-105-billion-300060453.html (accessed May 3, 2019).

18. Allen et al., "Reference Guide on the Estimation of Economic Damages," in *Reference Manual on Scientific Evidence*, 3rd ed., Federal Judicial Center, 2011.

19. Box, George E.P., "Use and Abuse of Regression," *Technometrics*, 8:4, 625-629, 1966.

20. Granger, C.W.J. and Newbold, P., "Spurious Regressions in Econometrics," *Journal of Econometrics*, 2, 111-120, 1974.

21. Kaye, David H. and Freedman, David A., "Reference Guide on Statistics" *Reference Manual on Scientific Evidence*, 3rd ed., Federal Judicial Center, 2011.

22. Noriega, A E, and Ventosa-Santaulària, D. "Spurious Regression and Trending Variables." *Oxford Bulletin of Economics and Statistics* 69 (2007): 439-444.

23. Phillips, P.C.B., "Understanding Spurious Regressions in Econometrics," *Journal of Econometrics*, 33, 311-340, 1986.

24. Rubinfeld, Daniel L., "Reference Guide on Multiple Regression" *Reference Manual on Scientific Evidence*, 3rd ed., Federal Judicial Center, 2011.

25. Yule, G Udny. "Why Do We Sometimes Get Nonsense-Correlations Between Time-Series?" *Journal of the Royal Statistical Society*, Vol. 89, No. 1 (Jan. 1926), pp. 1–63.

Attachment D: Janssen Share of Opioids Shipped to Dispensing Facilities in Cuyahoga and Summit Counties, Ohio

Table D.1
Janssen Share of Opioids Shipped to Dispensing Facilities in Cuyahoga and Summit Counties, Ohio

Net[1] Morphine Milligram Equivalents (MME, in Millions)
ARCOS Data from January 2006–December 2014

	Period		Janssen Opioids[2]		All Other Opioids		Total Opioids	
			MME (M)	Percent	MME (M)	Percent	MME (M)	Percent
1	2006–2014		240.3	1.6%	15,091.3	98.4%	15,331.6	100%
2	2006		47.8	4.7%	967.2	95.3%	1,015.0	100%
3	2007		28.7	2.3%	1,236.3	97.7%	1,265.0	100%
4	2008		18.4	1.3%	1,385.2	98.7%	1,403.5	100%
5	2009		19.3	1.2%	1,656.0	98.8%	1,675.3	100%
6	2010		28.1	1.5%	1,845.9	98.5%	1,873.9	100%
7	2011		26.4	1.4%	1,909.5	98.6%	1,935.9	100%
8	2012		26.8	1.4%	1,931.5	98.6%	1,958.3	100%
9	2013		23.9	1.2%	2,000.1	98.8%	2,024.0	100%
10	2014		21.0	1.0%	2,159.6	99.0%	2,180.6	100%
11	2006	January	5.3	6.2%	79.5	93.8%	84.8	100%
12		February	3.7	5.2%	68.2	94.8%	71.9	100%
13		March	4.5	7.5%	55.4	92.5%	59.9	100%
14		April	4.2	5.4%	73.2	94.6%	77.4	100%
15		May	4.3	4.8%	84.8	95.2%	89.1	100%
16		June	3.4	3.9%	83.6	96.1%	86.9	100%
17		July	4.1	4.7%	83.2	95.3%	87.2	100%
18		August	3.9	4.3%	86.8	95.7%	90.7	100%
19		September	3.0	3.5%	82.9	96.5%	86.0	100%
20		October	4.1	4.3%	91.4	95.7%	95.5	100%
21		November	3.5	3.9%	88.3	96.1%	91.9	100%
22		December	3.7	4.0%	89.9	96.0%	93.7	100%
23	2007	January	3.5	3.5%	95.4	96.5%	98.9	100%
24		February	3.1	3.3%	89.9	96.7%	93.0	100%
25		March	3.1	3.1%	95.0	96.9%	98.0	100%
26		April	2.6	2.6%	96.7	97.4%	99.3	100%
27		May	2.3	2.1%	105.8	97.9%	108.1	100%
28		June	2.4	2.2%	103.5	97.8%	105.8	100%
29		July	2.3	2.1%	108.7	97.9%	111.0	100%
30		August	1.9	1.7%	110.8	98.3%	112.7	100%
31		September	2.1	2.1%	99.6	97.9%	101.7	100%
32		October	1.4	1.2%	109.3	98.8%	110.7	100%
33		November	2.2	1.9%	115.2	98.1%	117.4	100%
34		December	1.9	1.7%	106.4	98.3%	108.3	100%

	Period		Janssen Opioids[2]		All Other Opioids		Total Opioids	
			MME (M)	Percent	MME (M)	Percent	MME (M)	Percent
35	2008	January	1.8	1.5%	113.9	98.5%	115.7	100%
36		February	1.4	1.3%	108.7	98.7%	110.2	100%
37		March	0.6	0.7%	83.3	99.3%	83.9	100%
38		April	1.4	1.2%	115.7	98.8%	117.1	100%
39		May	1.4	1.3%	114.1	98.7%	115.5	100%
40		June	1.1	1.0%	109.0	99.0%	110.1	100%
41		July	1.6	1.2%	128.9	98.8%	130.5	100%
42		August	1.3	1.2%	111.6	98.8%	112.9	100%
43		September	1.4	1.1%	125.7	98.9%	127.2	100%
44		October	2.4	1.8%	128.5	98.2%	130.9	100%
45		November	1.9	1.7%	111.4	98.3%	113.3	100%
46		December	2.0	1.5%	134.3	98.5%	136.3	100%
47	2009	January	0.6	0.5%	124.1	99.5%	124.8	100%
48		February	1.7	1.3%	128.1	98.7%	129.8	100%
49		March	1.4	1.0%	137.3	99.0%	138.7	100%
50		April	1.0	0.8%	136.0	99.2%	137.0	100%
51		May	1.2	0.9%	128.8	99.1%	129.9	100%
52		June	1.2	0.9%	141.0	99.1%	142.2	100%
53		July	1.8	1.3%	142.3	98.7%	144.1	100%
54		August	1.5	1.1%	135.2	98.9%	136.7	100%
55		September	1.8	1.2%	141.8	98.8%	143.5	100%
56		October	2.4	1.6%	148.9	98.4%	151.3	100%
57		November	2.3	1.7%	136.3	98.3%	138.6	100%
58		December	2.3	1.5%	156.4	98.5%	158.7	100%
59	2010	January	2.2	1.6%	139.4	98.4%	141.6	100%
60		February	2.3	1.6%	135.6	98.4%	137.8	100%
61		March	2.5	1.5%	160.3	98.5%	162.8	100%
62		April	2.3	1.5%	153.9	98.5%	156.2	100%
63		May	2.3	1.6%	141.9	98.4%	144.2	100%
64		June	2.5	1.5%	160.0	98.5%	162.4	100%
65		July	2.2	1.4%	153.9	98.6%	156.0	100%
66		August	2.2	1.4%	161.0	98.6%	163.3	100%
67		September	2.4	1.5%	156.6	98.5%	159.0	100%
68		October	2.3	1.4%	155.8	98.6%	158.0	100%
69		November	2.3	1.4%	162.7	98.6%	165.0	100%
70		December	2.6	1.6%	164.8	98.4%	167.5	100%

	Period		Janssen Opioids[2]		All Other Opioids		Total Opioids	
			MME (M)	Percent	MME (M)	Percent	MME (M)	Percent
71	2011	January	2.6	1.6%	164.4	98.4%	167.1	100%
72		February	1.6	1.1%	150.9	98.9%	152.5	100%
73		March	1.5	0.8%	170.0	99.2%	171.5	100%
74		April	2.0	1.3%	152.9	98.7%	154.9	100%
75		May	2.3	1.4%	161.0	98.6%	163.4	100%
76		June	2.6	1.5%	166.5	98.5%	169.1	100%
77		July	2.1	1.4%	148.7	98.6%	150.8	100%
78		August	2.3	1.4%	164.6	98.6%	166.9	100%
79		September	2.3	1.5%	153.9	98.5%	156.2	100%
80		October	2.2	1.4%	155.6	98.6%	157.8	100%
81		November	2.8	1.7%	157.5	98.3%	160.3	100%
82		December	2.1	1.3%	163.4	98.7%	165.5	100%
83	2012	January	2.4	1.5%	155.6	98.5%	158.0	100%
84		February	2.0	1.3%	153.0	98.7%	155.0	100%
85		March	2.5	1.5%	168.2	98.5%	170.7	100%
86		April	2.0	1.3%	154.0	98.7%	156.0	100%
87		May	2.4	1.4%	167.5	98.6%	169.9	100%
88		June	2.2	1.3%	158.4	98.7%	160.6	100%
89		July	2.3	1.4%	161.5	98.6%	163.9	100%
90		August	2.3	1.3%	172.1	98.7%	174.4	100%
91		September	2.1	1.5%	143.7	98.5%	145.8	100%
92		October	2.6	1.4%	174.5	98.6%	177.1	100%
93		November	2.0	1.2%	163.4	98.8%	165.4	100%
94		December	2.0	1.2%	159.7	98.8%	161.7	100%
95	2013	January	2.3	1.3%	174.3	98.7%	176.7	100%
96		February	1.9	1.3%	149.6	98.7%	151.5	100%
97		March	2.0	1.2%	159.0	98.8%	161.0	100%
98		April	1.9	1.1%	170.3	98.9%	172.2	100%
99		May	2.2	1.2%	171.2	98.8%	173.4	100%
100		June	1.6	1.0%	154.7	99.0%	156.3	100%
101		July	2.3	1.3%	178.7	98.7%	181.0	100%
102		August	2.0	1.1%	172.1	98.9%	174.1	100%
103		September	1.9	1.2%	164.3	98.8%	166.3	100%
104		October	1.9	1.1%	177.2	98.9%	179.1	100%
105		November	1.8	1.1%	158.7	98.9%	160.5	100%
106		December	2.1	1.2%	170.0	98.8%	172.0	100%

	Period		Janssen Opioids[2]		All Other Opioids		Total Opioids	
			MME (M)	Percent	MME (M)	Percent	MME (M)	Percent
107	2014	January	1.8	1.1%	166.5	98.9%	168.3	100%
108		February	1.9	1.2%	149.9	98.8%	151.7	100%
109		March	1.7	1.0%	164.7	99.0%	166.4	100%
110		April	1.7	1.0%	165.1	99.0%	166.8	100%
111		May	2.0	1.2%	172.1	98.8%	174.2	100%
112		June	1.8	1.1%	163.8	98.9%	165.5	100%
113		July	1.8	1.0%	182.5	99.0%	184.3	100%
114		August	1.7	1.0%	169.2	99.0%	170.9	100%
115		September	1.6	0.9%	179.2	99.1%	180.8	100%
116		October	1.8	0.6%	295.8	99.4%	297.6	100%
117		November	1.5	0.9%	163.4	99.1%	164.9	100%
118		December	1.8	1.0%	187.4	99.0%	189.2	100%

Notes: 1) Tabulation reflects net ARCOS transactions (sales, dispositions, transfers, purchases, returns, and unsolicited returns) by indicated time period, where buyer state is Ohio, counties are Summit and Cuyahoga, and buyer business type is not an analytical lab, distributor, exporter, manufacturer, or reverse distributor.
2) Janssen Opioids are Duragesic, Nucynta, Nucynta ER, Tylenol with codeine, and Tylox.

Sources: 1) ARCOS opioid data files:
confidential_arcos_20060101-20141231_all_states_20180621.txt,
confidential_arcos_20060101-20141231_all_states_20180625.txt, and
confidential_arcos_20060101-20141231_oh_wv_il_al_mi_fl_20180419_01.txt –
confidential arcos 20060101-20141231 oh wv il al mi fl 20180419 14.txt.
2) www.deadiversion.usdoj.gov/arcos/handbook/full.pdf
3) www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Opioid-Morphine-EQ-Conversion-Factors-April-2017.pdf
4) www.cdc.gov/drugoverdose/resources/data.html
5) www.fda.gov/industry/structured-product-labeling-resources/ndcnhric-labeler-codes

Table D.2
Janssen Share of Opioids Shipped to Dispensing Facilities in Cuyahoga County, Ohio

Net[1] Morphine Milligram Equivalents (MME, in Millions)
ARCOS Data from January 2006–December 2014

	Period		Janssen Opioids[2]		All Other Opioids		Total Opioids	
			MME (M)	Percent	MME (M)	Percent	MME (M)	Percent
1	2006–2014		134.0	1.4%	9,645.8	98.6%	9,779.8	100.0%
2	2006		24.4	3.8%	611.3	96.2%	635.7	100.0%
3	2007		15.0	1.8%	798.7	98.2%	813.7	100.0%
4	2008		10.2	1.1%	913.4	98.9%	923.6	100.0%
5	2009		10.2	0.9%	1,083.5	99.1%	1,093.7	100.0%
6	2010		15.6	1.3%	1,178.7	98.7%	1,194.3	100.0%
7	2011		16.1	1.3%	1,216.4	98.7%	1,232.5	100.0%
8	2012		16.0	1.3%	1,205.7	98.7%	1,221.7	100.0%
9	2013		13.7	1.1%	1,243.0	98.9%	1,256.7	100.0%
10	2014		12.8	0.9%	1,395.1	99.1%	1,407.9	100.0%
11	2006	January	2.9	5.4%	50.2	94.6%	53.0	100%
12		February	2.0	4.4%	43.7	95.6%	45.7	100%
13		March	2.3	8.4%	24.8	91.6%	27.1	100%
14		April	2.3	4.7%	45.7	95.3%	48.0	100%
15		May	2.4	4.1%	55.2	95.9%	57.5	100%
16		June	1.5	2.7%	53.7	97.3%	55.2	100%
17		July	1.9	3.4%	54.7	96.6%	56.6	100%
18		August	1.9	3.3%	54.8	96.7%	56.7	100%
19		September	1.4	2.5%	55.2	97.5%	56.6	100%
20		October	2.2	3.6%	59.2	96.4%	61.4	100%
21		November	2.0	3.5%	56.3	96.5%	58.4	100%
22		December	1.6	2.8%	57.8	97.2%	59.4	100%
23	2007	January	2.0	3.2%	60.1	96.8%	62.0	100%
24		February	1.5	2.5%	56.8	97.5%	58.3	100%
25		March	1.2	2.0%	61.5	98.0%	62.8	100%
26		April	1.1	1.7%	61.9	98.3%	63.0	100%
27		May	1.3	1.8%	68.3	98.2%	69.6	100%
28		June	1.1	1.6%	68.0	98.4%	69.1	100%
29		July	1.3	1.8%	70.1	98.2%	71.3	100%
30		August	1.1	1.5%	71.9	98.5%	73.0	100%
31		September	1.2	1.9%	62.8	98.1%	64.0	100%
32		October	0.9	1.3%	71.6	98.7%	72.5	100%
33		November	1.3	1.7%	76.8	98.3%	78.1	100%
34		December	1.1	1.5%	69.1	98.5%	70.1	100%

	Period		Janssen Opioids[2]		All Other Opioids		Total Opioids	
			MME (M)	Percent	MME (M)	Percent	MME (M)	Percent
35	2008	January	1.2	1.6%	75.1	98.4%	76.3	100%
36		February	0.9	1.2%	72.4	98.8%	73.3	100%
37		March	0.3	0.6%	54.4	99.4%	54.7	100%
38		April	0.5	0.7%	77.3	99.3%	77.9	100%
39		May	0.7	1.0%	74.8	99.0%	75.5	100%
40		June	0.4	0.5%	72.2	99.5%	72.6	100%
41		July	0.7	0.8%	86.4	99.2%	87.1	100%
42		August	0.8	1.0%	72.8	99.0%	73.6	100%
43		September	0.8	0.9%	84.1	99.1%	84.8	100%
44		October	1.6	1.9%	83.4	98.1%	85.0	100%
45		November	1.1	1.5%	72.0	98.5%	73.1	100%
46		December	1.2	1.4%	88.5	98.6%	89.7	100%
47	2009	January	0.3	0.4%	82.2	99.6%	82.6	100%
48		February	1.0	1.1%	85.9	98.9%	86.9	100%
49		March	0.7	0.8%	92.1	99.2%	92.8	100%
50		April	0.6	0.7%	88.2	99.3%	88.8	100%
51		May	0.7	0.8%	85.7	99.2%	86.4	100%
52		June	0.5	0.6%	92.8	99.4%	93.3	100%
53		July	1.1	1.2%	92.9	98.8%	94.0	100%
54		August	0.8	0.9%	88.3	99.1%	89.1	100%
55		September	0.9	1.0%	89.9	99.0%	90.8	100%
56		October	1.2	1.3%	95.1	98.7%	96.3	100%
57		November	1.1	1.3%	87.7	98.7%	88.8	100%
58		December	1.1	1.0%	102.7	99.0%	103.8	100%
59	2010	January	1.2	1.3%	89.9	98.7%	91.1	100%
60		February	1.2	1.4%	86.8	98.6%	88.0	100%
61		March	1.3	1.2%	103.8	98.8%	105.1	100%
62		April	1.2	1.2%	97.5	98.8%	98.7	100%
63		May	1.1	1.2%	91.7	98.8%	92.8	100%
64		June	1.3	1.3%	101.8	98.7%	103.1	100%
65		July	1.3	1.3%	96.6	98.7%	97.9	100%
66		August	1.2	1.2%	105.7	98.8%	106.9	100%
67		September	1.4	1.4%	97.4	98.6%	98.9	100%
68		October	1.4	1.4%	99.5	98.6%	100.9	100%
69		November	1.3	1.2%	103.5	98.8%	104.8	100%
70		December	1.6	1.5%	104.4	98.5%	106.0	100%

	Period		Janssen Opioids[2]		All Other Opioids		Total Opioids	
			MME (M)	Percent	MME (M)	Percent	MME (M)	Percent
71	2011	January	1.5	1.4%	106.3	98.6%	107.8	100%
72		February	1.0	1.1%	96.2	98.9%	97.2	100%
73		March	1.0	0.9%	107.1	99.1%	108.1	100%
74		April	1.2	1.2%	96.6	98.8%	97.8	100%
75		May	1.4	1.3%	103.7	98.7%	105.1	100%
76		June	1.6	1.5%	106.5	98.5%	108.0	100%
77		July	1.2	1.2%	95.5	98.8%	96.7	100%
78		August	1.5	1.4%	105.4	98.6%	106.9	100%
79		September	1.3	1.4%	97.3	98.6%	98.6	100%
80		October	1.3	1.3%	98.8	98.7%	100.1	100%
81		November	2.0	2.0%	100.4	98.0%	102.4	100%
82		December	1.1	1.1%	102.4	98.9%	103.6	100%
83	2012	January	1.4	1.5%	96.8	98.5%	98.3	100%
84		February	1.2	1.2%	97.9	98.8%	99.1	100%
85		March	1.7	1.5%	106.6	98.5%	108.2	100%
86		April	1.4	1.4%	97.4	98.6%	98.7	100%
87		May	1.3	1.3%	103.0	98.7%	104.3	100%
88		June	1.2	1.2%	99.7	98.8%	100.9	100%
89		July	1.4	1.4%	98.8	98.6%	100.2	100%
90		August	1.3	1.2%	106.6	98.8%	107.9	100%
91		September	1.2	1.3%	89.7	98.7%	90.9	100%
92		October	1.5	1.4%	108.2	98.6%	109.7	100%
93		November	1.1	1.1%	101.6	98.9%	102.7	100%
94		December	1.2	1.2%	99.5	98.8%	100.7	100%
95	2013	January	1.3	1.2%	105.3	98.8%	106.6	100%
96		February	1.1	1.2%	92.1	98.8%	93.2	100%
97		March	1.1	1.1%	99.2	98.9%	100.4	100%
98		April	1.1	1.0%	105.1	99.0%	106.2	100%
99		May	1.1	1.1%	104.2	98.9%	105.3	100%
100		June	1.0	1.0%	95.9	99.0%	96.9	100%
101		July	1.3	1.2%	110.9	98.8%	112.3	100%
102		August	1.2	1.1%	108.3	98.9%	109.5	100%
103		September	1.2	1.1%	104.3	98.9%	105.5	100%
104		October	1.1	1.0%	108.8	99.0%	109.9	100%
105		November	1.1	1.1%	102.8	98.9%	103.9	100%
106		December	1.1	1.1%	106.0	98.9%	107.1	100%

	Period		Janssen Opioids[2]		All Other Opioids		Total Opioids	
			MME (M)	Percent	MME (M)	Percent	MME (M)	Percent
107	2014	January	1.1	1.0%	103.7	99.0%	104.8	100%
108		February	1.2	1.3%	93.3	98.7%	94.5	100%
109		March	1.1	1.1%	102.6	98.9%	103.7	100%
110		April	1.0	1.0%	101.9	99.0%	102.9	100%
111		May	1.3	1.2%	108.0	98.8%	109.3	100%
112		June	1.1	1.0%	103.0	99.0%	104.1	100%
113		July	1.0	0.9%	115.3	99.1%	116.3	100%
114		August	0.9	0.9%	105.8	99.1%	106.7	100%
115		September	1.0	0.9%	114.1	99.1%	115.1	100%
116		October	1.1	0.5%	227.5	99.5%	228.6	100%
117		November	0.9	0.8%	101.9	99.2%	102.8	100%
118		December	1.2	1.0%	118.0	99.0%	119.2	100%

Notes: 1) Tabulation reflects net ARCOS transactions (sales, dispositions, transfers, purchases, returns, and unsolicited returns) by indicated time period, where buyer state is Ohio, buyer county is Cuyahoga, and buyer business type is not an analytical lab, distributor, exporter, manufacturer, or reverse distributor.
2) Janssen Opioids are Duragesic, Nucynta, Nucynta ER, Tylenol with codeine, and Tylox.

Sources: 1) ARCOS opioid data files:
confidential_arcos_20060101-20141231_all_states_20180621.txt,
confidential_arcos_20060101-20141231_all_states_20180625.txt, and
confidential_arcos_20060101-20141231_oh_wv_il_al_mi_fl_20180419_01.txt –
confidential arcos 20060101-20141231 oh wv il al mi fl 20180419 14.txt.
2) www.deadiversion.usdoj.gov/arcos/handbook/full.pdf
3) www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Opioid-Morphine-EQ-Conversion-Factors-April-2017.pdf
4) www.cdc.gov/drugoverdose/resources/data.html
5) www.fda.gov/industry/structured-product-labeling-resources/ndcnhric-labeler-codes

Table D.3
Janssen Share of Opioids Shipped to Dispensing Facilities in Summit County, Ohio

Net[1] Morphine Milligram Equivalents (MME, in Millions)
ARCOS Data from January 2006–December 2014

	Period		Janssen Opioids[2]		All Other Opioids		Total Opioids	
			MME (M)	Percent	MME (M)	Percent	MME (M)	Percent
1	2006–2014		106.3	1.9%	5,445.5	98.1%	5,551.8	100.0%
2	2006		23.4	6.2%	355.9	93.8%	379.3	100.0%
3	2007		13.7	3.0%	437.6	97.0%	451.3	100.0%
4	2008		8.2	1.7%	471.8	98.3%	479.9	100.0%
5	2009		9.1	1.6%	572.6	98.4%	581.6	100.0%
6	2010		12.5	1.8%	667.2	98.2%	679.7	100.0%
7	2011		10.3	1.5%	693.1	98.5%	703.4	100.0%
8	2012		10.8	1.5%	725.8	98.5%	736.6	100.0%
9	2013		10.2	1.3%	757.1	98.7%	767.3	100.0%
10	2014		8.2	1.1%	764.5	98.9%	772.7	100.0%
11	2006	January	2.4	7.6%	29.4	92.4%	31.8	100%
12		February	1.7	6.6%	24.5	93.4%	26.2	100%
13		March	2.2	6.9%	30.6	93.1%	32.8	100%
14		April	1.9	6.5%	27.5	93.5%	29.4	100%
15		May	1.9	6.1%	29.6	93.9%	31.5	100%
16		June	1.9	6.0%	29.9	94.0%	31.8	100%
17		July	2.2	7.1%	28.4	92.9%	30.6	100%
18		August	2.0	5.9%	32.0	94.1%	34.0	100%
19		September	1.6	5.5%	27.7	94.5%	29.3	100%
20		October	1.9	5.6%	32.2	94.4%	34.1	100%
21		November	1.5	4.5%	32.0	95.5%	33.5	100%
22		December	2.1	6.1%	32.1	93.9%	34.2	100%
23	2007	January	1.5	4.1%	35.3	95.9%	36.8	100%
24		February	1.6	4.6%	33.1	95.4%	34.7	100%
25		March	1.9	5.3%	33.4	94.7%	35.3	100%
26		April	1.5	4.0%	34.8	96.0%	36.3	100%
27		May	1.0	2.7%	37.5	97.3%	38.5	100%
28		June	1.3	3.5%	35.5	96.5%	36.8	100%
29		July	1.1	2.7%	38.6	97.3%	39.7	100%
30		August	0.8	2.0%	38.9	98.0%	39.8	100%
31		September	0.9	2.5%	36.8	97.5%	37.7	100%
32		October	0.4	1.2%	37.7	98.8%	38.1	100%
33		November	0.9	2.2%	38.5	97.8%	39.3	100%
34		December	0.8	2.0%	37.4	98.0%	38.2	100%

	Period		Janssen Opioids[2]		All Other Opioids		Total Opioids	
			MME (M)	Percent	MME (M)	Percent	MME (M)	Percent
35	2008	January	0.6	1.4%	38.8	98.6%	39.4	100%
36		February	0.6	1.6%	36.3	98.4%	36.9	100%
37		March	0.3	1.0%	28.9	99.0%	29.2	100%
38		April	0.8	2.1%	38.4	97.9%	39.2	100%
39		May	0.7	1.8%	39.3	98.2%	40.0	100%
40		June	0.7	1.9%	36.8	98.1%	37.5	100%
41		July	0.9	2.1%	42.4	97.9%	43.4	100%
42		August	0.6	1.4%	38.8	98.6%	39.4	100%
43		September	0.7	1.5%	41.7	98.5%	42.3	100%
44		October	0.8	1.6%	45.1	98.4%	45.9	100%
45		November	0.8	2.0%	39.4	98.0%	40.2	100%
46		December	0.8	1.7%	45.8	98.3%	46.6	100%
47	2009	January	0.3	0.7%	41.9	99.3%	42.2	100%
48		February	0.7	1.7%	42.2	98.3%	42.9	100%
49		March	0.7	1.5%	45.2	98.5%	45.9	100%
50		April	0.4	0.9%	47.7	99.1%	48.2	100%
51		May	0.5	1.1%	43.0	98.9%	43.5	100%
52		June	0.7	1.4%	48.2	98.6%	48.9	100%
53		July	0.7	1.4%	49.4	98.6%	50.1	100%
54		August	0.7	1.4%	46.9	98.6%	47.6	100%
55		September	0.8	1.6%	51.9	98.4%	52.7	100%
56		October	1.2	2.2%	53.8	97.8%	55.0	100%
57		November	1.2	2.3%	48.6	97.7%	49.8	100%
58		December	1.2	2.3%	53.7	97.7%	55.0	100%
59	2010	January	1.1	2.1%	49.5	97.9%	50.5	100%
60		February	1.0	2.1%	48.8	97.9%	49.8	100%
61		March	1.2	2.1%	56.5	97.9%	57.7	100%
62		April	1.1	1.9%	56.4	98.1%	57.4	100%
63		May	1.2	2.2%	50.3	97.8%	51.4	100%
64		June	1.2	2.0%	58.2	98.0%	59.3	100%
65		July	0.9	1.5%	57.2	98.5%	58.1	100%
66		August	1.0	1.8%	55.4	98.2%	56.4	100%
67		September	1.0	1.6%	59.2	98.4%	60.2	100%
68		October	0.8	1.4%	56.3	98.6%	57.1	100%
69		November	1.0	1.7%	59.1	98.3%	60.2	100%
70		December	1.0	1.7%	60.4	98.3%	61.5	100%

	Period		Janssen Opioids[2]		All Other Opioids		Total Opioids	
			MME (M)	Percent	MME (M)	Percent	MME (M)	Percent
71	2011	January	1.1	1.9%	58.1	98.1%	59.2	100%
72		February	0.6	1.0%	54.7	99.0%	55.3	100%
73		March	0.5	0.7%	62.9	99.3%	63.4	100%
74		April	0.8	1.5%	56.2	98.5%	57.1	100%
75		May	0.9	1.6%	57.3	98.4%	58.2	100%
76		June	1.0	1.7%	60.1	98.3%	61.1	100%
77		July	0.9	1.7%	53.2	98.3%	54.1	100%
78		August	0.8	1.4%	59.2	98.6%	60.0	100%
79		September	1.0	1.7%	56.6	98.3%	57.6	100%
80		October	0.9	1.6%	56.8	98.4%	57.7	100%
81		November	0.8	1.3%	57.0	98.7%	57.8	100%
82		December	0.9	1.5%	61.0	98.5%	61.9	100%
83	2012	January	1.0	1.6%	58.7	98.4%	59.7	100%
84		February	0.7	1.3%	55.1	98.7%	55.8	100%
85		March	0.8	1.3%	61.6	98.7%	62.4	100%
86		April	0.7	1.1%	56.7	98.9%	57.3	100%
87		May	1.1	1.6%	64.5	98.4%	65.5	100%
88		June	0.9	1.6%	58.7	98.4%	59.7	100%
89		July	0.9	1.5%	62.7	98.5%	63.6	100%
90		August	1.0	1.5%	65.5	98.5%	66.5	100%
91		September	1.0	1.7%	54.0	98.3%	54.9	100%
92		October	1.0	1.5%	66.3	98.5%	67.3	100%
93		November	0.9	1.5%	61.8	98.5%	62.7	100%
94		December	0.8	1.3%	60.2	98.7%	61.0	100%
95	2013	January	1.0	1.4%	69.1	98.6%	70.1	100%
96		February	0.8	1.5%	57.5	98.5%	58.3	100%
97		March	0.9	1.4%	59.7	98.6%	60.6	100%
98		April	0.8	1.2%	65.2	98.8%	65.9	100%
99		May	1.0	1.5%	67.0	98.5%	68.0	100%
100		June	0.7	1.1%	58.8	98.9%	59.4	100%
101		July	1.0	1.4%	67.8	98.6%	68.8	100%
102		August	0.8	1.2%	63.8	98.8%	64.6	100%
103		September	0.7	1.2%	60.0	98.8%	60.7	100%
104		October	0.8	1.2%	68.4	98.8%	69.2	100%
105		November	0.7	1.2%	56.0	98.8%	56.7	100%
106		December	0.9	1.4%	64.0	98.6%	64.9	100%

	Period		Janssen Opioids[2]		All Other Opioids		Total Opioids	
			MME (M)	Percent	MME (M)	Percent	MME (M)	Percent
107	2014	January	0.7	1.1%	62.8	98.9%	63.5	100%
108		February	0.7	1.2%	56.6	98.8%	57.2	100%
109		March	0.6	1.0%	62.1	99.0%	62.7	100%
110		April	0.7	1.1%	63.2	98.9%	63.9	100%
111		May	0.8	1.2%	64.1	98.8%	64.9	100%
112		June	0.7	1.1%	60.7	98.9%	61.4	100%
113		July	0.8	1.1%	67.2	98.9%	68.0	100%
114		August	0.7	1.1%	63.4	98.9%	64.1	100%
115		September	0.6	0.9%	65.1	99.1%	65.7	100%
116		October	0.7	1.0%	68.3	99.0%	69.0	100%
117		November	0.6	1.0%	61.5	99.0%	62.1	100%
118		December	0.7	0.9%	69.4	99.1%	70.0	100%

Notes: 1) Tabulation reflects net ARCOS transactions (sales, dispositions, transfers, purchases, returns, and unsolicited returns) by indicated time period, where buyer state is Ohio, buyer county is Summit, and buyer business type is not an analytical lab, distributor, exporter, manufacturer, or reverse distributor.
2) Janssen Opioids are Duragesic, Nucynta, Nucynta ER, Tylenol with codeine, and Tylox.

Sources: 1) ARCOS opioid data files:
confidential_arcos_20060101-20141231_all_states_20180621.txt,
confidential_arcos_20060101-20141231_all_states_20180625.txt, and
confidential_arcos_20060101-20141231_oh_wv_il_al_mi_fl_20180419_01.txt –
confidential arcos 20060101-20141231 oh wv il al mi fl 20180419 14.txt.
2) www.deadiversion.usdoj.gov/arcos/handbook/full.pdf
3) www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Opioid-Morphine-EQ-Conversion-Factors-April-2017.pdf
4) www.cdc.gov/drugoverdose/resources/data.html
5) www.fda.gov/industry/structured-product-labeling-resources/ndcnhric-labeler-codes

Attachment E: Rosenthal Model B Variations

Attachment E: Rosenthal Model B Variations

Rosenthal Model B Variations

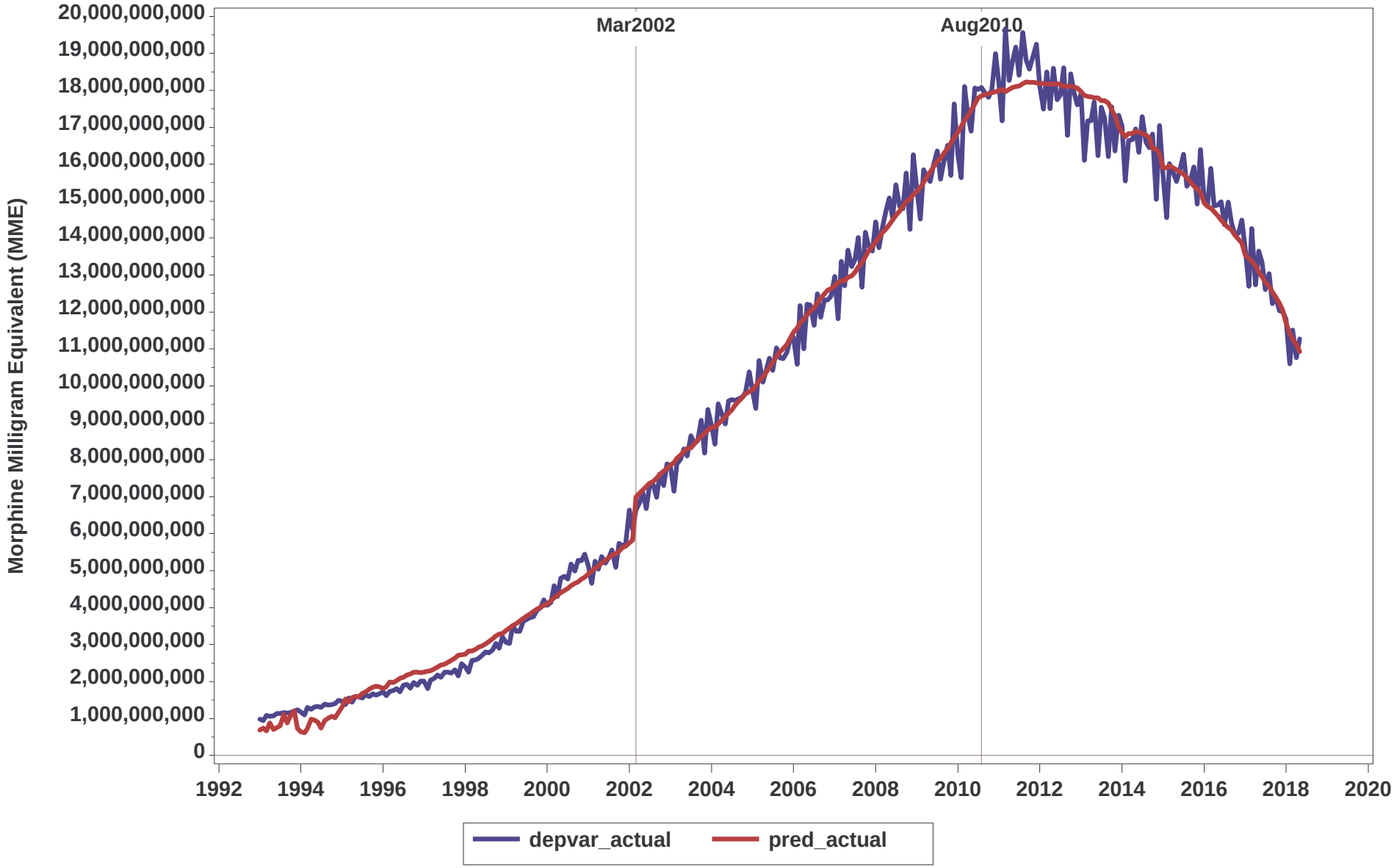
Regression Estimates: Impact of [Explanatory Factor] on Sales in MMEs, 1993-2018

Param.	Parameters Label	Model A Estimate	Sig.	Model B Estimate	Sig.	Model C Estimate	Sig.	[A] Model B Replication		[B] *Reverse* Contacts History		[C] *Scramble* Contacts History		[D] "Contacts" = constant 40,000 for all months		[E] "Contacts" = Mauna Loa CO_2 (ppm×100)		[F] Contacts = 0 for All Months but January		[G] Contacts = 0 for All Months After Dec 2000		[H] Contacts = 0 for All Months After Dec 1993	
α	Constant	5,667,453,793	***	2,447,050,075	***	2,823,448,831	***	2,447,050,075	***	2,300,597,120	***	1,610,266,163	***	1,604,148,858	***	1,593,428,999	***	2,485,142,947	***	2,546,180,812	***	616,068,171	
β	Stock of Promotion	2,965	***	.		.																	
β_1	Stock of Promotion*Regime Dummy until Mar2002	.		934	***	878	***	934	***	1,038	***	1,006	***	841	***	93,672	***	11,294	***	835	***	4,952	***
β_2	Stock of Promotion*Dummy from Mar2002	.		1,111	***	1,064	***	1,111	***	1,344	***	1,294	***	1,067	***	118,706	***	13,507	***	1,118	***	6,420	***
β_3	Stock of Promotion*Dummy Trend from Aug2010	.		-8	***	-8	***	-8	***	-10	***	-10	***	-8	***	-870	***	-97	***	-8	***	-46	***
δ	Depreciation Rate Constant	0.0005		-0.0067	***	-0.0070	***	-0.0067	***	-0.0061	***	-0.0057	***	-0.0060	***	-0.0058	***	-0.0069	***	-0.0094	***	-0.0085	***
γ_1	Consensus Statement From AAPM/APS 01/1998	.		.		-208,998,427																	
γ_2	Federation of State Medical Boards Guidelines 01/1999	.		.		434,599,302	**																
γ_3	JCAHO pain standards released 01/2001(*)	.		.		4,733,839																	
γ_4	OxyContin Reformulation 08/2010	.		.		107,939,744																	
γ_5	Hydrocodone Rescheduling 10/2014	.		.		552,145,343	***																
γ_6	Aggregate Price Index	-7,689,846,168	***	-1,947,298,967	***	-2,233,428,201	***	-1,947,298,967	***	-1,334,245,762	***	-1,095,330,437	**	-1,084,146,014	**	-1,069,151,818	**	-2,060,703,371	***	-2,013,181,464	***	-1,917,779,488	***
RSquare		0.8811		0.9937		0.9939		0.9937		0.9937		0.9935		0.9936		0.9937		0.9928		0.9935		0.9907	
AdjRSq		0.8799		0.9936		0.9937		0.9936		0.9936		0.9934		0.9935		0.9936		0.9927		0.9934		0.9906	

Rosenthal Figure D.2: Variation [A]

Actual and Predicted Actual MME EUTRx

MME_EUTRx = (a) + (b1*ddr_Mar2002 + b2*dd_Mar2002 + b3*dt_Aug2010)*(stock_promo) + main0*agg_price_ndx

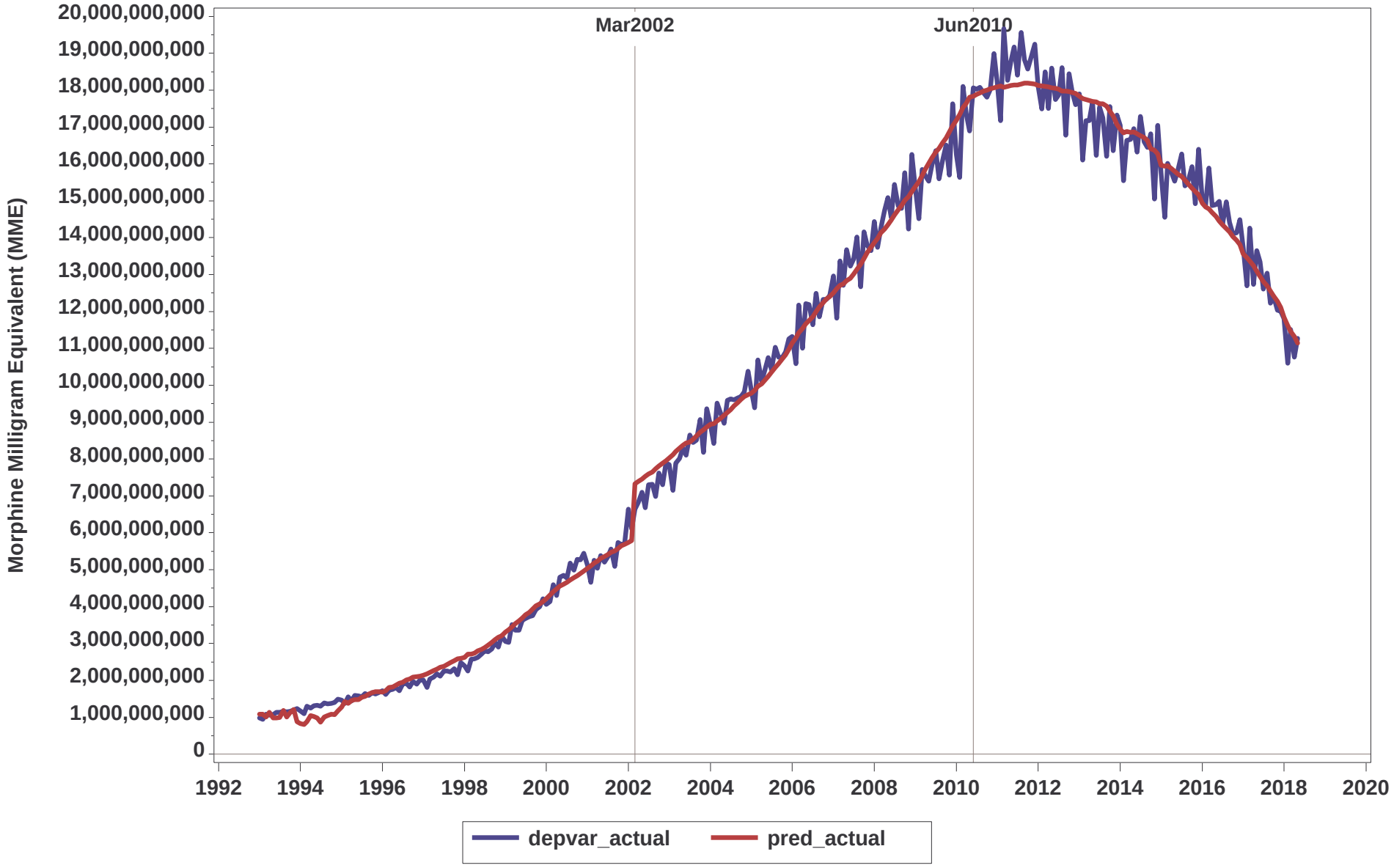


Source: IQVIA NPA, ARCOS, and CDC.

Rosenthal Figure D.2: Variation [B]

Actual and Predicted Actual MME EUTRx substituting reversed monthly detailing contacts for monthly detailing contacts

MME_EUTRx = (a) + (b1*ddr_Mar2002 + b2*dd_Mar2002 + b3*dt_Jun2010)*(stock_promo)
+ main0*agg_price_ndx

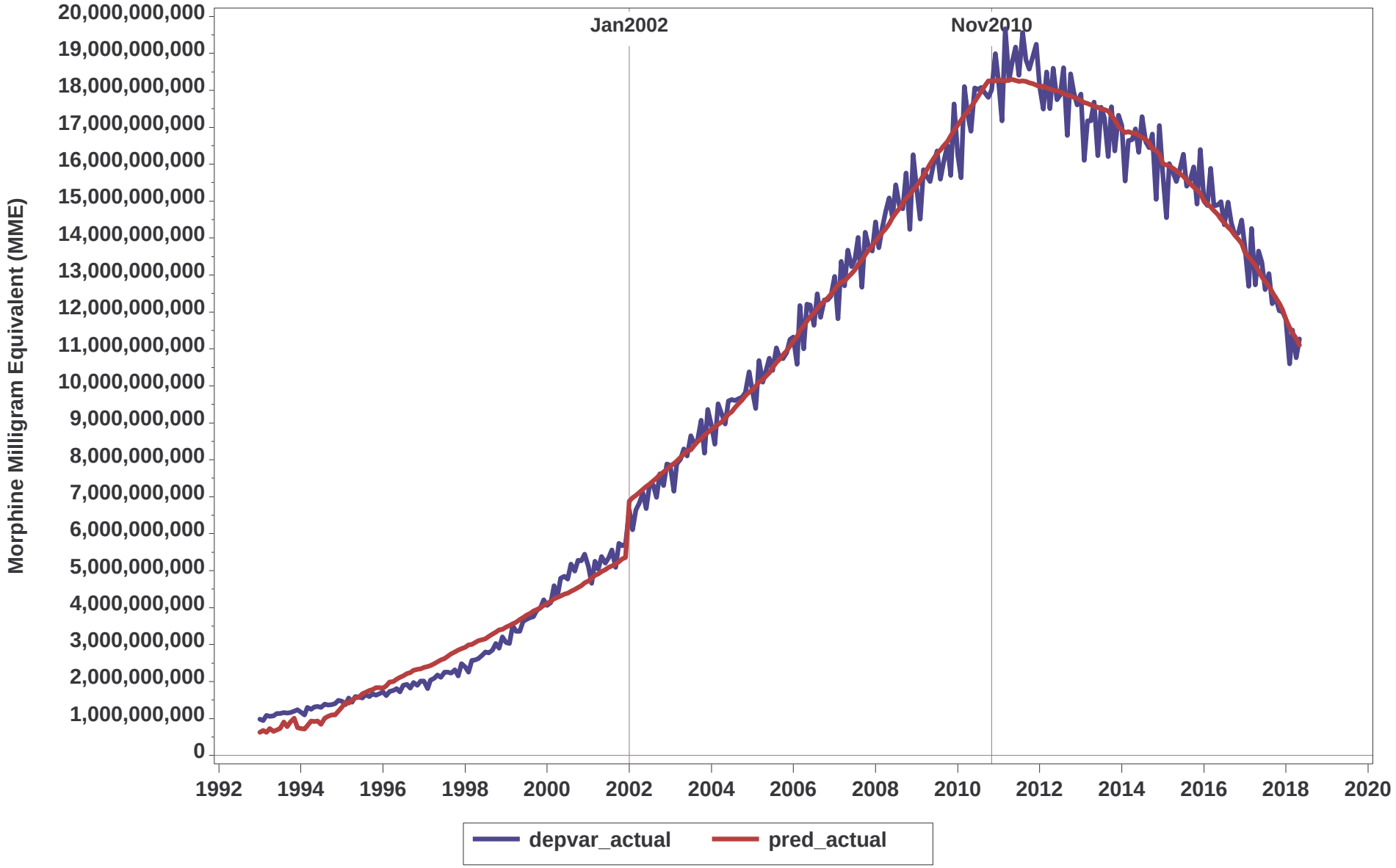


Source: IQVIA NPA, ARCOS, and CDC.

Rosenthal Figure D.2: Variation [C]

Actual and Predicted Actual MME EUTRx substituting scrambled monthly detailing contacts for monthly detailing contacts

MME_EUTRx = (a) + (b1*ddr_Jan2002 + b2*dd_Jan2002 + b3*dt_Nov2010)*(stock_promo)
+ main0*agg_price_ndx

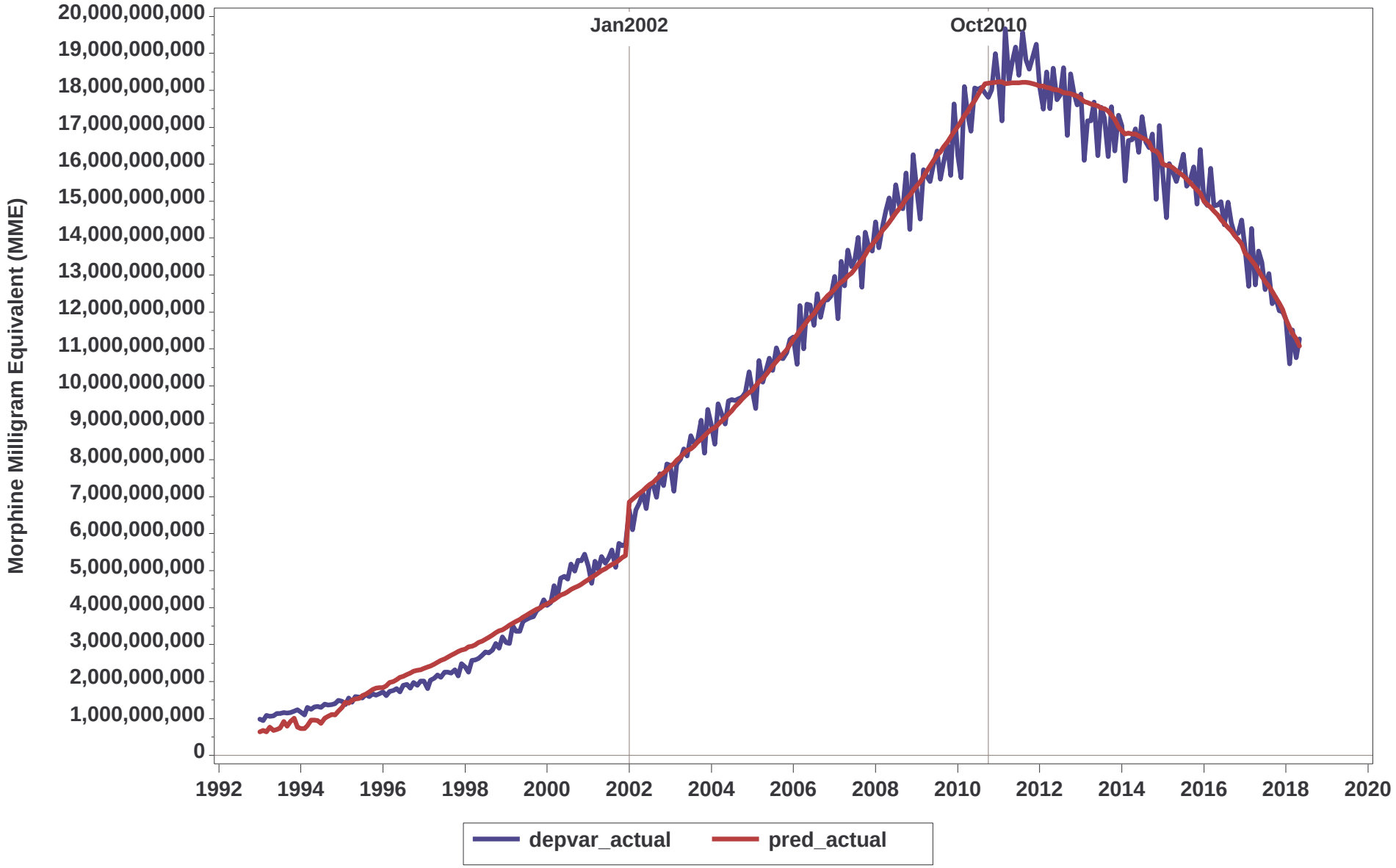


Source: IQVIA NPA, ARCOS, and CDC.

Rosenthal Figure D.2: Variation [D]

Actual and Predicted Actual MME EUTRx substituting 40,000 for monthly detailing contacts

MME_EUTRx = (a) + (b1*ddr_Jan2002 + b2*dd_Jan2002 + b3*dt_Oct2010)*(stock_promo)
+ main0*agg_price_ndx

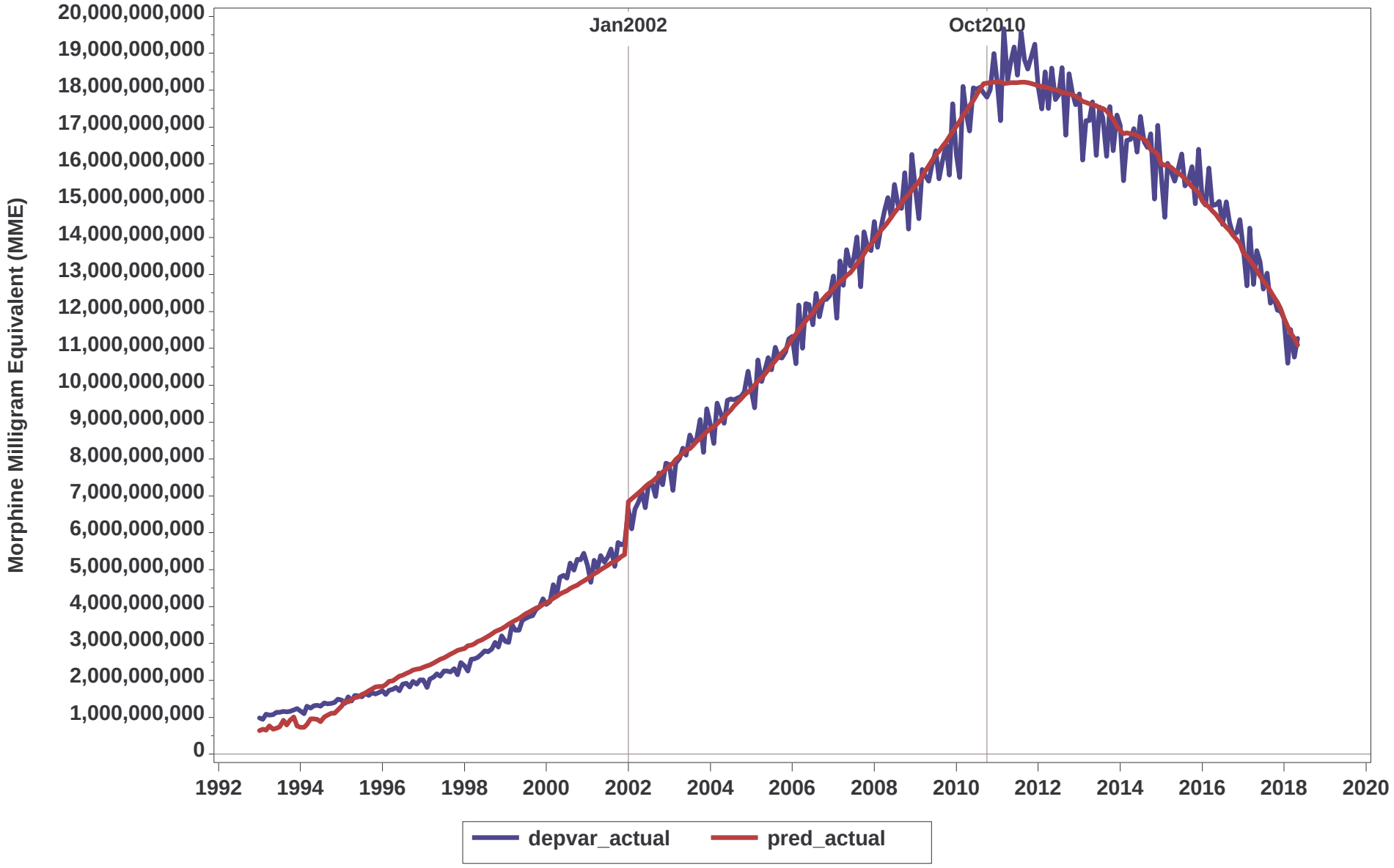


Source: IQVIA NPA, ARCOS, and CDC.

Rosenthal Figure D.2: Variation [E]

Actual and Predicted Actual MME EUTRx substituting monthly average Mauna Loa CO_2 for monthly detailing contacts

MME_EUTRx = (a) + (b1*ddr_Jan2002 + b2*dd_Jan2002 + b3*dt_Oct2010)*(stock_promo)
+ main0*agg_price_ndx

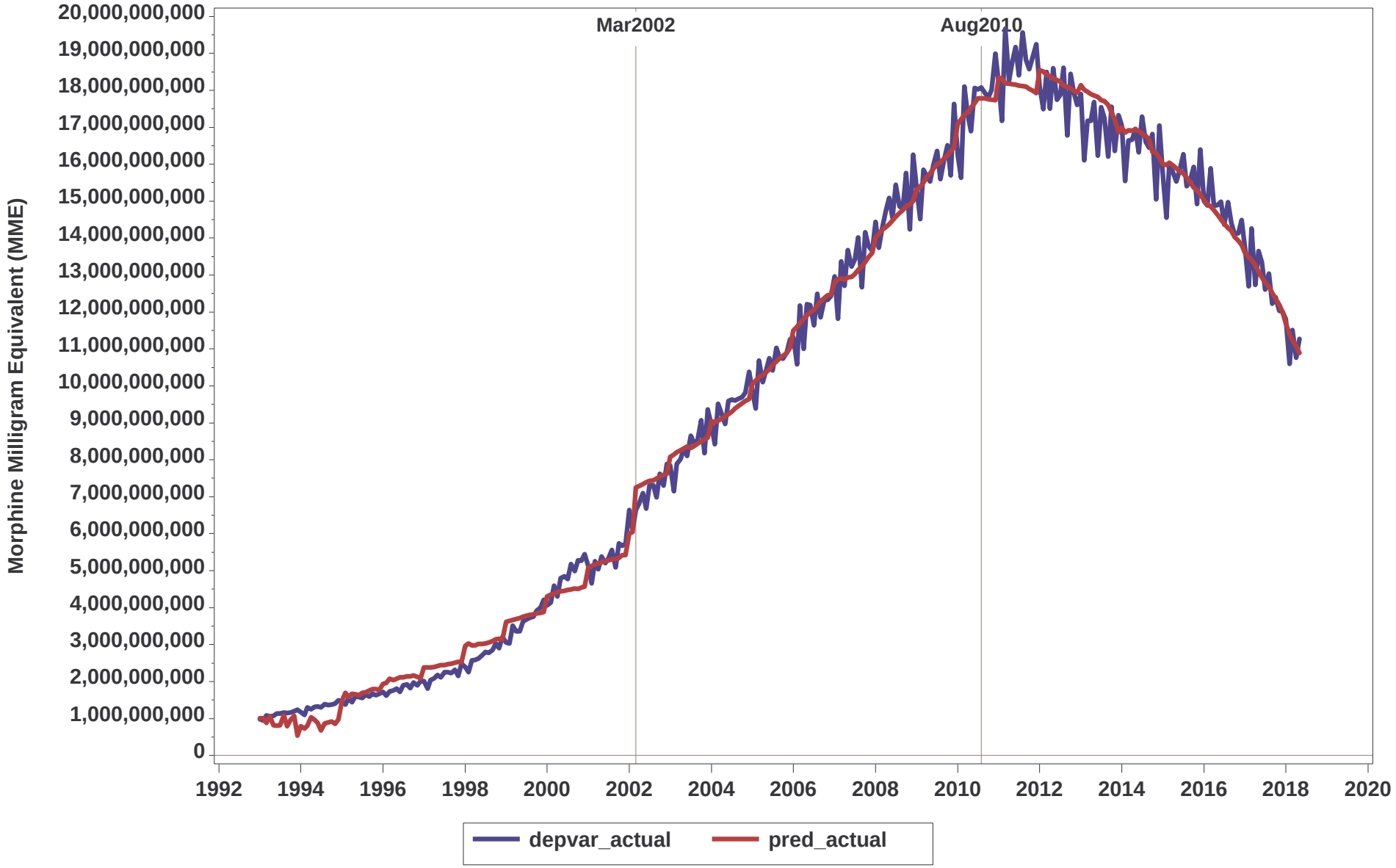


Source: IQVIA NPA, ARCOS, and CDC.

Rosenthal Figure D.2: Variation [F]

Actual and Predicted Actual MME EUTRx setting non–January detailing contacts to 0

MME_EUTRx = (a) + (b1*ddr_Mar2002 + b2*dd_Mar2002 + b3*dt_Aug2010)*(stock_promo)
+ main0*agg_price_ndx

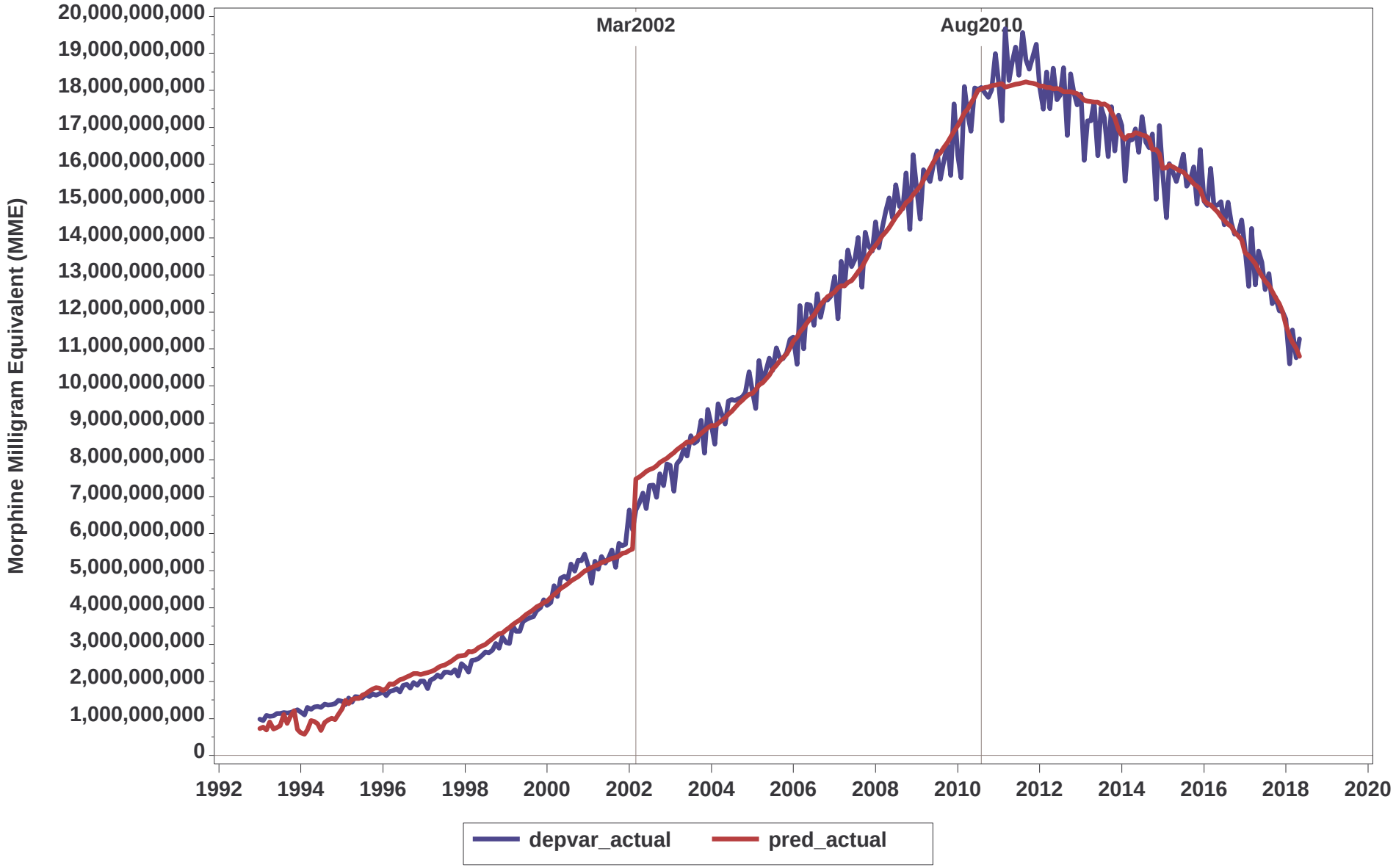


Source: IQVIA NPA, ARCOS, and CDC.

Rosenthal Figure D.2: Variation [G]

Actual and Predicted Actual MME EUTRx setting post–2000 detailing contacts to 0

MME_EUTRx = (a) + (b1*ddr_Mar2002 + b2*dd_Mar2002 + b3*dt_Aug2010)*(stock_promo) + main0*agg_price_ndx

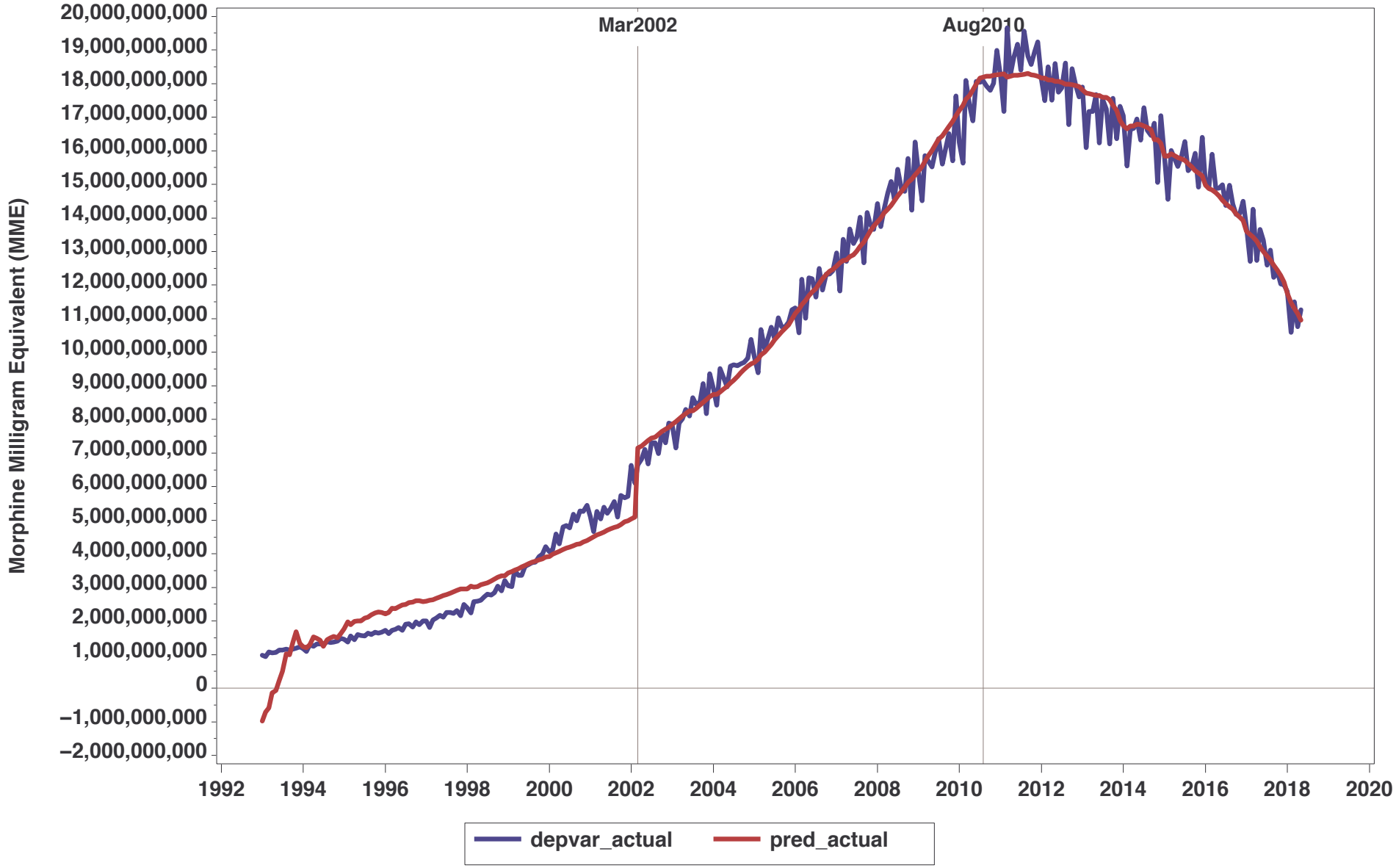


Source: IQVIA NPA, ARCOS, and CDC.

Rosenthal Figure D.2: Variation [H]

Actual and Predicted Actual MME EUTRx setting post−1993 detailing contacts to 0

MME_EUTRx = (a) + (b1*ddr_Mar2002 + b2*dd_Mar2002 + b3*dt_Aug2010)*(stock_promo) + main0*agg_price_ndx



Source: IQVIA NPA, ARCOS, and CDC.